

1 UNITED STATES DISTRICT COURT
2 NORTHERN DISTRICT OF OHIO
3 EASTERN DIVISION

4 - - - - - X
5 IRON WORKERS LOCAL UNION :
6 NO. 17 INSURANCE FUND, et al., :
7 Plaintiffs, :
8 v. : Civil Action No.:
9 PHILIP MORRIS, INCORPORATED, : 1:97 CV 1422
10 et al., :

11 Defendants. :
12 - - - - - X

13 Washington, D.C.

14 Monday, November 23, 1998

15 Deposition of ROBERT D. VERHALEN, a
16 witness herein, called for examination by counsel
17 for Plaintiffs in the above-entitled matter,
18 pursuant to agreement, the witness being duly
19 sworn by JAN A. WILLIAMS, a Notary Public in and
20 for the District of Columbia, taken at the
21 offices of Shook, Hardy, & Bacon, LLP, Suite 600,
22 801 Pennsylvania Avenue, N.W., Washington, D.C.,
23 at 10:15 a.m., Monday, November 23, 1998, and the
24 proceedings being taken down by Stenotype by JAN
25 A. WILLIAMS, RPR, and transcribed under her

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direction.

APPEARANCES:

On behalf of the Plaintiffs:

RICHARD G. PICCIONI, ESQ.

1916 Pike Place, No. 12-203

Seattle, Washington 98101-1056

206-443-1344

On behalf of the Defendant Lorillard Tobacco
Company:

THOMAS A. DUNCAN, ESQ.

Shook, Hardy & Bacon, LLP

One Kansas City Place

1200 Main Street

Kansas City, Missouri 64105-2118

816-474-6550

ALSO PRESENT:

WILLIAM J. THOMPSON

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C O N T E N T S

WITNESS EXAMINATION BY COUNSEL FOR
 ROBERT D. VERHALEN PLAINTIFFS
 By Mr. Piccioni 4

Afternoon Session - Page 70

E X H I B I T S

VERHALEN-OHIO EXHIBIT NO. PAGE NO.

1 - Expert report of Robert D. Verhalen
 dated 11/5/98 8
 2 - Surgeon General's Report dated 1989 55
 3 - Article entitled Accuracy of Cancer Death
 Certificates and Its Effect on Cancer
 Mortality Statistics 63
 4 - Article entitled The Health Care Costs of
 Smoking 123
 5 - Expert report of Robert D. Verhalen
 dated 7/1/97 134

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P R O C E E D I N G S

Whereupon,

ROBERT D. VERHALEN,

was called as a witness by counsel for
Plaintiffs, and having been duly sworn by the
Notary Public, was examined and testified as
follows:

EXAMINATION BY COUNSEL

FOR PLAINTIFFS

BY MR. PICCIONI:

Q. Would you please state your name for
the record.

A. Robert D. Verhalen.

Q. Dr. Verhalen, my name is Richard
Piccioni, I'm one of the attorneys for the
plaintiffs in this case. I'll be taking your
deposition today. And I know you've had your
deposition taken before, correct?

A. Yes.

Q. And I know you're familiar with the
procedure. But just to be sure, if there's
anything that I ask that is in any way unclear,
will you agree to not answer those questions but
rather ask me to rephrase them?

A. Yes.

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1 Q. What is your understanding as to whom
2 you are to bill for your time here today?

3 A. Well, I usually just send my bill
4 directly to Shook, Hardy & Bacon.

5 Q. And how late are you prepared to stay
6 today for this deposition?

7 A. Well, my understanding is that you're
8 allowed seven hours. So I'm prepared to stay
9 seven hours from whenever our beginning time was.

10 Q. Which was ten o'clock.

11 A. Right.

12 Q. Your preferences about taking a break
13 at lunch?

14 A. I really don't have a preference, we
15 can have something brought in, we can take a
16 short break.

17 Q. Fine.

18 A. But at my age I need an occasional head
19 break.

20 Q. Okay, fine, just let me know. Did you
21 bring any documents with you today?

22 A. I brought my report.

23 Q. And what was your understanding about
24 the document request that accompanied this?

25 A. Well, I have not seen a subpoena for

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1 this particular session so I didn't bother
2 bringing anything else. But, going on the basis
3 of history with the last testimony, I believe
4 that it was not necessary to bring anything that
5 was from published sources or that you already
6 had. So that's the premise I'm operating under.

7 Q. Are there any notes or any other
8 materials that you developed in the course of
9 preparing for your testimony or preparing that
10 report?

11 A. No.

12 Q. Doctor, when were you first contacted
13 about testifying in the Ohio case, the Iron
14 Workers case?

15 A. Gee, I checked all the dates on this.
16 Probably a month or six weeks ago.

17 Q. And who contacted you about that?

18 A. I was contacted by Shook, Hardy & Bacon
19 attorneys.

20 Q. Who in particular?

21 A. Probably Keith Borman.

22 Q. You are also an expert witness in the
23 Northwest Laborers case?

24 A. That's correct.

25 Q. And I take it you were contacted about

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1 testifying or appearing as a witness in the Ohio
2 case after your deposition in the Northwest
3 Laborers case?

4 A. It may not have been after the
5 deposition. I can't remember the exact dates,
6 but somewhere around there. Probably just before
7 that deposition.

8 Q. How much time have you spent on
9 preparing for the Iron Workers case? I'll refer
10 to it as the Ohio case.

11 A. Okay. I really don't know exactly
12 because I was working on another case up until
13 the time that it was stayed. I could only
14 guess.

15 Q. Go ahead and guess.

16 A. Perhaps 100 hours.

17 Q. What did that work entail generally?

18 A. Well, the entire 100 would not
19 necessarily have been me. I have staff who will
20 pull documents for me. So some of that would be
21 them. But pulling documents, reviewing the
22 documents that were prepared by the plaintiffs'
23 witnesses, and then preparing my report.

24 Q. The report which you prepared in this
25 case, is it related to the report which you

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1 prepared in the Northwest Laborers case in the
2 sense that information in the former was used in
3 the latter?

4 A. To a substantial extent, that's true.

5 MR. PICCIONI: If we could mark as
6 Exhibit 1 Dr. Verhalen's report in the Ohio
7 case.

8 (Verhalen-Ohio Exhibit No. 1
9 was marked for identification.)

10 BY MR. PICCIONI:

11 Q. Could you look at your report on page
12 7. The last full paragraph on that page, the
13 last sentence of that paragraph, if you could
14 read that sentence.

15 A. The same would hold true?

16 Q. Yes.

17 A. For circumstances in which decisions
18 were to be made about who owes what to whom for
19 real or imagined grievances such as in the
20 current action regarding the Ohio Insurance
21 Fund's payments for treatment of smoking-related
22 diseases in the northwest. I'm sorry. In the
23 northwest was a carryover from the previous
24 report.

25 Q. Also, in the following paragraph,

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1 there's a sentence that begins with the word
2 plaintiffs, plaintiffs in this action. Could you
3 read that one.

4 A. Plaintiffs in this action, however,
5 seek damages for at least the 28 period 1979 to
6 2007.

7 Q. That was 28-year period?

8 A. Yes.

9 Q. And what was the basis of that time
10 period?

11 A. I would have to go back and look at the
12 report. It's entirely possible this is a typo
13 also carried over. What I did was I took my
14 Northwest report, made a copy of it, and then
15 made the changes necessary to produce this
16 report, adding in what I felt was necessary.
17 Now, I thought I had corrected all these, but I
18 would have to check the report.

19 Q. And that process that you just
20 described did not involve the printing and
21 hand-editing of the Northwest Laborers report?

22 A. Sometimes I will do that when I've
23 completed the report and then I'll go through and
24 do a hand-editing process. Why I wouldn't have
25 picked this up I'm not quite sure. But then I'll

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1 just destroy the hand-edited copy. The only copy
2 I keep is my electronic version.

3 Q. Did the process that you describe
4 involve any form of communication with defense
5 counsel?

6 A. No, it did not.

7 Q. Do you have a copy of Appendix B to
8 this report with you?

9 A. I don't have it with me. Appendix B
10 was the article by -- on the ICD-9. I don't have
11 that attached to my copy. Again that was from a
12 published source.

13 Q. Doctor, have you ever taught a course
14 in epidemiology?

15 A. Not in epidemiology per se, no, I have
16 not.

17 Q. Statistics?

18 A. No.

19 Q. Have you published any papers
20 describing original research in the field of
21 epidemiology?

22 A. No, I have not.

23 Q. Have you served on the editorial boards
24 of any epidemiological journals?

25 A. No, I have not.

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1 Q. Sat on the thesis committee of a
2 graduate student in epidemiology?

3 A. Not in epidemiology, no.

4 Q. In any other field?

5 A. Yes.

6 Q. What field was that?

7 A. In health administration.

8 Q. Have you reviewed grant applications
9 for funding for epidemiological research?

10 A. Yes, I have.

11 Q. When was that?

12 A. That was through the mid to late
13 eighties and perhaps into the early nineties,
14 maybe '90, '91.

15 Q. For what granting agency?

16 A. For the Centers for Disease Control.

17 Q. What study section was that?

18 A. This was for the Center for Injury and
19 Violence Prevention. I was on the committee
20 dealing with epidemiologic studies.

21 Q. Doctor, can you explain to me the
22 difference between a confounder and an effect
23 modifier?

24 A. A confounder and an effect modifier?
25 If I understand you correctly, that effect

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1 modifier would be design effect, is that what
2 you're talking about?

3 Q. How about effect of an exposure?

4 A. Well, I'm not familiar with the term in
5 that context. Effect modifier as an effective
6 exposure?

7 Q. Well, if you think of -- I'm trying not
8 to answer the question.

9 Are you familiar with the term
10 noncollapsibility as it applies to odds ratios?

11 A. Not as it applies to odds ratios, but
12 in a generic sense I am.

13 Q. Could you explain to me what that term
14 means in a generic sense.

15 A. Noncollapsibility is when a -- would be
16 when a data stream or a set of data have been
17 gathered in a very specific sense but may have
18 overlapping or nonmutually exclusive categories,
19 you cannot collapse them into smaller groups for
20 purposes of comparison or analysis.

21 Q. What's a multiplicative interaction?

22 A. A multiplicative interaction would be
23 one in which there are more than a single
24 influence on a particular disease category.
25 There may be, for instance, a variety of causes

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1 or presumed causes of a particular condition, any
2 one of which may by themselves, in an additive or
3 in a multiplicative sense, exacerbate the
4 problem; synergy, if you will.

5 Q. Are both additive and multiplicative
6 interactions considered synergistic?

7 A. Not necessarily. They may be.
8 Multiplicative frequently are.

9 Q. If you have a multiplicative
10 interaction between two exposures, what is the
11 relationship between the relative risks for each
12 exposure and both exposures?

13 A. That's difficult to say. It would
14 relate largely to the degree to which the various
15 influences are associated. If they are
16 multiplicative in a very, very strong sense, two
17 to one, three to one, four to one, one has a much
18 stronger synergy on the other, it might have an
19 exacerbating effect; if it were in the reverse,
20 it may have an ameliorating effect.

21 Q. Can you give me an example of two
22 exposures that interact in a multiplicative
23 manner?

24 A. I haven't given it any thought.
25 Sitting here it's a little difficult to come up

1 with one right offhand.

2 Q. If exposure A interacts in a
3 multiplicative way with exposure B, does the
4 relative risk for A change in the presence of B?

5 A. It might, yes.

6 Q. Doctor, do you regularly attend
7 conferences in the field of epidemiology?

8 A. When I can get away.

9 Q. Which is how frequently?

10 A. In the last couple of years, I have
11 not.

12 Q. Couple meaning?

13 A. Meaning since '95, late '95.

14 Q. And prior to that?

15 A. I used to try to attend regularly.

16 Q. Do you know personally people who you
17 think of as being well-recognized
18 epidemiologists?

19 A. Yes.

20 Q. Could you name some of them.

21 A. Sure. Vernon Houk.

22 Q. Anyone else?

23 A. I'm trying to think of the new dean of
24 the School of Public Health at Chapel Hill, he
25 used to be the head of the Centers For Disease

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1 Control. Bill Roper.

2 Q. Anybody else?

3 A. Brian McMahon. I mean we could go
4 through a litany here. How many do we want to
5 name?

6 Q. Kenneth Rothman?

7 A. I'm not familiar with Kenneth Rothman.

8 Q. Sander Greenland?

9 A. I've heard the name, but I'm not
10 familiar with it.

11 Q. Demitrious Trichopoulos?

12 A. No, I'm not familiar.

13 Q. David Savitz?

14 A. David Savitz I know.

15 Q. Dr. Fraumeni?

16 A. Yes, by reputation.

17 Q. But not personally?

18 A. Not personally.

19 Q. Have you collaborated with any of these
20 people that you've named in research projects?

21 A. Not directly, no.

22 Q. I understand, Doctor, that you were the
23 director of epidemiology at the CPSC from 1972 to
24 1995; is that correct?

25 A. That's correct.

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1 Q. Does that post still exist?

2 A. Yes, it does.

3 Q. Who is the present director?

4 A. I do not know her name, it just -- when
5 I left the agency, they collapsed two
6 organizations. And they brought a woman in who
7 is basically a laboratory scientist. And she is
8 the director of epidemiology.

9 Q. That makes sense I suppose.

10 A. Not to me. Politics.

11 Q. Does the CPSC consider cigarettes to be
12 consumer products?

13 A. Yes and no. There's not a clear answer
14 to that. Tobacco was explicitly excluded from
15 the Consumer Product Safety Act. But, under the
16 Secretary for Health and Human Services, when
17 they wanted to look at a fire safe cigarette, the
18 CPSC was given the lead by The White House I
19 believe in setting it up. So to that extent CPSC
20 was involved in cigarettes as a product, but just
21 with respect to flammability.

22 Q. What is the role of epidemiology in the
23 operations of the CPSC?

24 A. The charter for the directorate for
25 epidemiology in CPSC was embodied in Section 5 of

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1 the act in which it stated the commission shall
2 establish and maintain a clearinghouse to
3 collect, investigate, and analyze injury and
4 illness information as related to products. So,
5 as the director of epidemiology, I led the
6 organization which did those four functions.

7 Q. What would be the purpose of collecting
8 such information?

9 A. To identify areas for further research
10 to get at the causes of injury.

11 Q. How would you -- strike that.
12 Can you give me an example of that
13 purpose being served in the case of a particular
14 product for which epidemiological studies were
15 done by the CPSC?

16 A. Sure. When we noticed a fairly large
17 number of injuries associated with chain saws, we
18 identified cases through our surveillance system
19 for follow-up to determine exactly how the
20 accident occurred; at which point, after
21 accumulating a number of investigations, we were
22 able to identify kickback as one of the major
23 scenarios leading to serious injury and death.

24 And that led to the development of
25 laboratory tests of various chain saws which went

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1 beyond the epidemiology. Now we had identified
2 where the basic problem was.

3 And the laboratory then took that
4 information to identify exactly -- or to design a
5 study to test exactly how much kickback came from
6 different types of chain saws with different
7 types of chains under different conditions which
8 we had identified for them as potentially
9 relevant.

10 Q. Did I hear this right, that the
11 epidemiological study of chain saw accidents led
12 to the identification of kickback?

13 A. Led to the identification of relevant
14 circumstances in the accident that warranted
15 direct study to see exactly how the injuries
16 occurred and what could be done to prevent them.

17 Q. So I'm just remembering wrong, that I
18 thought you said identified kickback as the
19 occurrence that was leading to the injuries?

20 A. Well, as one of several relevant
21 scenarios that led to injury.

22 Q. Kickback leads to injury?

23 A. Not inevitably. I'm sorry.

24 Q. You didn't hear the word if in the
25 beginning of that.

1 A. Okay.

2 Q. I'm sorry. How did you determine that
3 kickback led to injury?

4 A. We conducted investigations of a sample
5 of chain saw-related injuries which were reported
6 to us from hospital emergency rooms. When we
7 conducted those investigations, we saw -- we
8 learned what events took place immediately before
9 leading up to the event itself and immediately
10 after to -- so that we had a relatively good
11 picture of what happened.

12 In some of these cases, a kickback
13 was -- figured prominently as one of several
14 causes of injury which were being treated in the
15 emergency rooms. As a consequence of that, we
16 decided that kickback warranted a closer look to
17 see exactly how it occurred, under what
18 circumstances it occurred, and tried to get a
19 handle on how often it occurred without injury as
20 well as with injury. That was a laboratory
21 function.

22 They instrumented chain saws and took
23 high-speed videotapes with chain saws being used
24 by professionals under a variety of circumstances
25 and were able to determine what kinds of chain

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1 led to the strongest kickback, what kinds of
2 chain saws, models and brands, had the strongest
3 kickback, and made several judgments as to which
4 might have been the greatest -- the strongest
5 factors in leading to kickback that would be
6 sufficient to actually kick back far enough to
7 hit the user, the operator.

8 And that led then to a number of other
9 experiments into different kinds of low kickback
10 chains in an effort to reduce the extent of
11 kickback. You couldn't prevent it entirely, but
12 you could reduce it.

13 Q. I'm interested really in the very
14 beginning of that answer.

15 A. Sure.

16 Q. The part that involves the
17 epidemiological methods. I take it that you
18 looked at several instances of accidents
19 involving chain saws?

20 A. Hundreds.

21 Q. And you developed a statistical
22 association between what?

23 A. Various accident scenarios and injury
24 by severity of injury and type of injury.

25 Q. The presence or absence of kickback was

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1 determined how?

2 A. By direct investigation and questions
3 of the victim or bystanders.

4 Q. As in the chain saw kicked back, a
5 description like that perhaps from the injured
6 person?

7 A. Yes, or my foot slipped and the log
8 allowed the chain to go down and hit my foot.
9 Kickback was not the only kind of injury, it was
10 just one of the most frequent.

11 Q. Was there a statistical association
12 between the occurrence of kickback and the
13 severity of the injury?

14 A. No, nor would I have expected there to
15 have been. You don't measure events that don't
16 lead to injury in a situation such as we had
17 here. We had a surveillance system which
18 involved hospital emergency rooms reporting to a
19 central source.

20 And kickback occurs literally hundreds
21 of times any time one uses a chain saw. They
22 don't necessarily lead to injury. Just as many
23 things occur, feet slip, people trip, and so on,
24 they're not necessarily injured.

25 In cases where they're injured, we

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1 simply listed them by frequency of injury and
2 severity of injury in any particular scenario and
3 decided where we would focus our energies first
4 to get at the details that led to kickback.

5 Q. You mean, every time that a chain saw
6 kicks back, it doesn't cause an injury?

7 A. No.

8 Q. But sometimes it does cause an injury?

9 A. It depends on the position and attitude
10 of the operator, how high the chain saw kicks
11 back, whether it kicks back typically 20 degrees
12 under full power or 30 degrees or 40 degrees and
13 where it hits him, if at all. In some cases
14 kickback may cause the chain saw to go very high,
15 but the person is able to avoid it as it comes
16 up.

17 Q. In your preceding answer, you said
18 something like under certain circumstances
19 kickback leads to injury?

20 A. Yes.

21 Q. In my question I asked you if kickback
22 always caused injury. Is there a difference
23 between the word leads to and cause?

24 A. No, I don't think so.

25 Q. So, going back a couple of questions,

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1 are you saying that you used epidemiological
2 studies to determine whether kickback led to
3 injuries with chain saws; am I correct?

4 A. No, to determine how kickback led to
5 chain saws. First what kinds of injuries were
6 associated with the use of chain saws; of the
7 kinds of injuries that were associated with chain
8 saws, which seemed to lead to the most serious
9 kinds of injuries or the most frequent injuries;
10 and, having identified those by surveillance or
11 descriptive epidemiology, if you will, we passed
12 it on to the engineers who then took the accident
13 scenarios and designed laboratory experiments to
14 get at exactly how kickback led to injury.

15 Q. But the epidemiological studies
16 persuaded you to some level of confidence that
17 kickback led to injuries?

18 A. Was one source of injuries.

19 Q. That kickback caused injuries?

20 A. Kickback could cause injuries.

21 Q. That kickback increased the risk of
22 injury?

23 A. That kickback -- without kickback there
24 would be no risk of injury from kickback, but
25 there would be other injuries. Kickback was just

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1 one type of injury.

2 Q. That measures taken to prevent kickback
3 would decrease the incidence of injury?

4 A. It would decrease the incidence of
5 kickback injury.

6 Q. Based on epidemiological studies?

7 A. Yes.

8 Q. What are the characteristics of
9 epidemiological findings, say, those in
10 particular you could use as an example, if it's
11 helpful in answering the question, that are
12 persuasive in leading to an inference of a
13 cause-and-effect relationship?

14 A. In the product safety area in which we
15 were operating, cause-and-effect relationships
16 were pretty clear on the surface of them when you
17 conducted an investigation. A, you either had an
18 injury in association with a chain saw or you did
19 not; B, if you had an injury with a chain saw, it
20 occurred in one of several different ways; C, if
21 you ranked these ways, you can decide which ones
22 you want to put your next dollars on to determine
23 exactly how and why those events are occurring;
24 D, once you've identified the ways they are
25 occurring and developed remedial measures and

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1 implemented those remedial measures, following
2 sufficient time for the market penetration of the
3 changes to occur in new products, you should see
4 a decline in that type of injury from that
5 particular cause.

6 Q. And those are all epidemiological
7 observations?

8 A. In the product safety area, yes. Let
9 me correct that last statement. When you said
10 they're all epidemiological observations, all
11 except the laboratory portion. Everything
12 leading up to the laboratory portion and then
13 evaluating the effect of the laboratory portion
14 is descriptive of epidemiology.

15 Q. Doctor, is it safe to say that the goal
16 of the CPSC is the introduction of safer products
17 into the U.S. market?

18 A. No. The goal of CPSC is to reduce
19 injuries associated with consumer products.

20 Q. Is one of the ways that that goal could
21 be achieved that there be changes in product
22 design that improve the safety of products?

23 A. Yes.

24 Q. Can you give me an example of a product
25 that exists now that existed 25 years ago and is

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1 in some respects safer than it was 25 years ago,
2 the same product but somehow safer?

3 A. Chain saws is one example.

4 Q. Are there products that are less safe
5 than they were 25 years ago?

6 A. In what context? After having taken
7 action based on CPSC action?

8 Q. Just can you think of a product,
9 something that I would go into a store and buy,
10 that in some respects is less safe now than it
11 was 25 years ago?

12 A. That's difficult to answer the way
13 you've phrased it.

14 Q. Can you identify the difficulty in the
15 phrasing?

16 A. Well, product life is a highly variable
17 entity. And some products which have a fairly
18 long life in use such as roller skates will
19 modify over time in such a way that they are
20 still basically the same product, but there are
21 sufficient differences in them as a result of
22 modern technology that they're used in a
23 different context which makes them more unsafe.

24 Q. Thank you. That actually helps me
25 understand. I had an example in mind, sofas.

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1 Sofas, and correct me if I'm wrong, on a market
2 share basis, now are more likely to be filled
3 with polyurethane foam padding rather than some
4 kind of cellulose-based padding. And I
5 understand, and correct me if I'm wrong, that in
6 some respects polyurethane foam presents certain
7 safety issues or presents them in a way which is
8 more problematic than older cellulose fill?

9 A. That may be. I'm not personally
10 familiar with the characteristics of polyurethane
11 foam or cellulose. I expect you're speaking with
12 respect to flammability?

13 Q. Yes.

14 A. And off-gassing. I know there are
15 issues, I don't know exactly what those issues
16 are. I would be more inclined to use an example
17 like roller skates which have morphed into Roller
18 Blades which puts them in a different
19 environment. They are much higher speed.

20 They're still basically roller skates,
21 but now they're in-line skates. I said Roller
22 Blades, that's a trade name, I should say in-line
23 skates. And they tend to be used more often in
24 the situation which leads the user into conflict
25 with automobiles and other kinds of problems.

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1 And I consider them less safe than the old
2 sidewalk roller skate.

3 Q. Plus kids today are out of their minds,
4 right?

5 A. Well, that's your characterization, not
6 mine.

7 Q. Are cigarettes safer than they used to
8 be 25 years ago?

9 A. I can't answer that question, I really
10 don't know.

11 MR. DUNCAN: Objection to the form of
12 the question, lack of foundation.

13 THE WITNESS: I guess the premise that
14 cigarettes were unsafe is one that might be
15 raised here. Whether or not I would agree with
16 whether or not they were unsafe, they certainly
17 are not safer from a flammability standpoint
18 because I know that's what we had looked at at
19 CPSC.

20 There has been no change in the
21 propensity for ignition of upholstered
22 furniture. But that's as much a problem with the
23 furniture and its flammability as it is with the
24 source of ignition.

25 BY MR. PICCIONI:

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1 Q. Doctor, I understand that, since
2 retiring from CPSC, you are working under the
3 auspices of an organization called Verhalen &
4 Associates; is that correct?

5 A. That's correct.

6 Q. What kind of work does that
7 organization do?

8 A. Basically we do research into hazards
9 that people ask about that are within our area of
10 competence. And we had started out originally as
11 product safety and helped people to understand
12 what the data that are collected by the federal
13 government mean and what they do not mean.

14 Q. When you say people, can you give me an
15 example without revealing anything that's of
16 proprietary nature of the kind of person that
17 you're talking about?

18 A. Sure. Anybody who has a need to
19 understand what the data with respect to products
20 that are put out by the Consumer Products Safety
21 Commission mean and what they don't mean. In
22 some cases those may be manufacturers, in some
23 cases they may be trade associations, and in some
24 cases they're researchers who are trying to work
25 with the data and they're not quite sure how to

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1 get it, and we show them how to get it and how to
2 interpret it.

3 Q. Are they ever defendants in products
4 liability suits?

5 A. Yes, they are.

6 Q. If you were to apportion the fraction
7 of the work that's performed by Verhalen &
8 Associates into that which is performed in
9 connection with a products liability suit and
10 that which is not, what would that mix be?

11 A. Probably 90 to 95 percent would be in
12 association with some kind of a product liability
13 suit, you know, probably 90 to 95 percent.

14 Q. And within that portion can you tell me
15 what fraction of it is work that is being paid
16 for by defendants in products liability suits as
17 opposed to plaintiffs?

18 A. I would say 75 to 80 percent.

19 Q. Does the work on products liability
20 suits ever entail offering an opinion about
21 whether a product defect was a cause of injury?

22 A. Not quite exactly that way. It
23 generally tends more to be whether or not a
24 particular product characteristic is in some way
25 causally associated with an injury.

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1 Q. In those cases in which you are
2 providing services for the plaintiffs in a
3 products liability case, have any of those
4 situations involved work such as you just
5 described in your previous answer; that is, work
6 in which a characteristic of the product is shown
7 to have a causal association with an injury?

8 A. Yes.

9 Q. Can you give me an example of that?

10 A. The one case I'm involved in here is on
11 hold at the moment, it's still in litigation, and
12 I really can't discuss the product without
13 revealing the industry.

14 One that is not on hold but it's early
15 enough that I can get into it probably without
16 revealing it involves not a consumer product in
17 the normal sense but a medication in this
18 particular case, tetanus toxoid, and
19 Guillain-Barre syndrome, where the defendant is
20 trying to claim that a particular case of
21 Guillain-Barre syndrome was not the result of
22 tetanus toxoid.

23 On the basis of epidemiologic rarity, I
24 contend that epidemiology cannot be used in this
25 context to say that it is not associated any more

1 than it could be to say that it was associated.
2 But the potential exists. And it involves an
3 organization within the government which is
4 supposed to be responsible for making payments to
5 persons who have been injured by the use of
6 inoculation or immunization shots.

7 Q. Can you think of another example?

8 A. As I said, the only one I can think
9 of -- the only other one I can think of is in
10 sort of a sensitive stage right now of
11 development.

12 Q. But at least --

13 A. Actually there are two of them there in
14 development now that I think about it.

15 Q. But at least in principle I as an
16 attorney might come to you and say review the
17 epidemiological literature concerning a drug and
18 incidence of an adverse medical condition because
19 I represent a person who developed that condition
20 after taking that drug. That such a request --
21 this isn't a sentence, but such a request would
22 fall within the ambit of the kind of work that
23 your organization might do?

24 A. It might be a part of it. It would
25 kind of depend on what it is they asked me to

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1 do. Usually they're asking me to give them some
2 kind of an opinion on what the literature says
3 about a particular situation.

4 But it's not -- it's not like they can
5 get me to review it from one perspective. I'll
6 review the literature critically and here's my
7 opinion. And that has led to the loss of some
8 clients.

9 Q. So maybe a better example would be that
10 I come to you as an attorney and ask you whether
11 you think that a causal relationship between
12 taking the drug and the injury is supported by
13 the epidemiological evidence?

14 A. A question could be phrased that way.
15 Generally I'm not approached by someone who says
16 do you think that such and such is true. I
17 generally get a situation where they come in
18 and -- well, let me use as an example
19 snowblowers, where I was asked to review the data
20 that had been available over the past 15 years on
21 snowblower-related accidents and render an
22 opinion as to how I think those accidents are
23 occurring insofar as the data will permit me to
24 render that opinion.

25 After I did that, it did lead to

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1 further work in that area, where they asked me to
2 try to collect additional information on
3 snowblowers.

4 Q. I take it in that instance there was
5 some feature of snowblowers that was at issue?

6 A. Not so much a feature of snowblowers
7 but a type of injury, finger amputation.

8 Q. And snowblowers generally?

9 A. Snowblowers generally.

10 Q. Where was the epidemiology?

11 A. Well, I didn't characterize that as an
12 epidemiologic inquiry. But you asked me what
13 kinds of things could you as a lawyer come and
14 ask. And these are among the things that you
15 could come and ask.

16 The epidemiology would be probably in
17 the second stage, where we begin doing some
18 primary data collection of our own on the
19 distribution of snowblowers with certain features
20 that the data showed to be associated with finger
21 amputation.

22 MR. DUNCAN: It's been about an hour
23 and a half. I wonder if this might be an
24 appropriate time for a break.

25 (Recess.)

1 BY MR. PICCIONI:

2 Q. Doctor, when we started the break, I
3 was asking you about the kind of work that
4 Verhalen & Associates performs or could be
5 expected to perform on behalf of a plaintiff in a
6 products liability suit. And my question is
7 really this, under what circumstances,
8 circumstances related to the epidemiological
9 literature dealing with a certain hazard, under
10 what circumstances would you render an opinion
11 that that epidemiological literature was
12 supportive of a cause-and-effect relationship
13 between a hazard and an injury?

14 MR. DUNCAN: Objection as to form.

15 THE WITNESS: I'm honestly not certain
16 I followed the question. Under what
17 circumstances would I render an opinion whether
18 or not the epidemiological literature supported
19 an association?

20 BY MR. PICCIONI:

21 Q. Supported a causal association.

22 A. Difficult to answer that in a vacuum.
23 A causal association requires a lot more than
24 just epidemiology. To my mind causal association
25 requires also demonstration of the cause and

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1 effect controlling for other known potential
2 causes, not just epidemiologically, because there
3 are a variety of things that you can't control in
4 the epidemiological context except
5 statistically. That has its own limitations. So
6 I really can't answer that question.

7 Both my batteries are going bad at the
8 same time here.

9 MR. DUNCAN: You want to take a break?

10 THE WITNESS: No. We'll go along while
11 they're still working.

12 BY MR. PICCIONI:

13 Q. Can epidemiological observations
14 increase the likelihood that a cause-and-effect
15 relationship exists between an exposure and
16 disease?

17 A. May I repeat the question to make sure
18 I understand it. Can epidemiological
19 observations increase the likelihood that a
20 causal relationship exists? No.

21 MR. DUNCAN: Excuse me. I wonder if we
22 can just go ahead and take a break.

23 (Discussion off the record.)

24 BY MR. PICCIONI:

25 Q. Have you ever rendered an opinion about

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1 whether something is likely to be true?

2 MR. DUNCAN: Objection as to form.

3 THE WITNESS: In any context?

4 BY MR. PICCIONI:

5 Q. Any context.

6 A. Sure.

7 Q. Have you ever rendered an opinion about
8 whether a cause-and-effect relationship likely
9 exists?

10 MR. DUNCAN: Objection as to form.

11 THE WITNESS: I guess I probably have
12 at some point. I can't think of one right now.
13 But where a causal relationship probably exists,
14 again in any context, I'm sure I have.

15 BY MR. PICCIONI:

16 Q. Do the findings of epidemiological
17 studies -- strike that.

18 Are there circumstances under which the
19 findings of epidemiological studies can
20 contribute to your forming the opinion that a
21 cause-and-effect relationship probably exists?

22 MR. DUNCAN: Objection as to form.

23 THE WITNESS: Not to the extent of the
24 use of the term probably. I would be more
25 inclined to say that epidemiologic data could

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1 reach the point that I would say it may exist and
2 it requires further investigation.

3 BY MR. PICCIONI:

4 Q. And by probably are you referring to
5 the likelihood being greater that the proposition
6 is true than that the proposition is false?

7 MR. DUNCAN: Objection as to form, that
8 misstates his testimony.

9 THE WITNESS: I didn't say probably. I
10 said not to the extent of probably. I said that
11 the epidemiologic literature could lead me to the
12 conclusion that a relationship -- a causal
13 relationship may exist. I would not say probably
14 because to me the term probably carries with it a
15 little more definitive judgment than I think
16 epidemiology is capable of making by itself.

17 BY MR. PICCIONI:

18 Q. If I take an ordinary legitimate pack
19 of cards and I remove from the pack ten diamonds,
20 I reshuffle the pack thoroughly, the remainder of
21 the pack thoroughly, is the card on the top of
22 the deck probably black?

23 A. It will have -- I'm trying to remember
24 the numbers in cards. We're talking 52 to a
25 deck, you're removing ten fifty-seconds of the

1 reds, I have to do the numbers. It might be more
2 likely to be black than red because there are
3 more black cards. I can't give you the exact
4 figure without doing the arithmetic.

5 Q. Just so we're on the same wavelength as
6 far as the meanings of words that mean different
7 things in different contexts, when I use the word
8 probably, I simply mean what you just said, that
9 it's more likely true than not true.

10 MR. DUNCAN: Objection as to form.

11 BY MR. PICCIONI:

12 Q. Does that help you answer my question?

13 A. Well, if that means that it's more
14 likely true than not true but not necessarily
15 more than 50 percent likely, yes, I can accept
16 that. It's a standard probability equation.

17 Q. If I take a deck of cards, a standard
18 legitimate deck of cards, and I remove a single
19 diamond, shuffle thoroughly, is the card that
20 turns up on the top of the deck probably red?

21 A. No, not necessarily.

22 Q. Is it more likely than not to be red?

23 MR. DUNCAN: Objection as to form.

24 THE WITNESS: You would be reducing the
25 likelihood of a red by taking out a red.

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1 BY MR. PICCIONI:

2 Q. Is it more likely to be black?

3 A. In a strict probability sense, it's
4 more likely to be black, one fifty-second more
5 likely or somewhere around there.

6 Q. So epidemiological evidence standing
7 alone could never persuade you that a
8 cause-and-effect relationship is more likely true
9 than not true?

10 A. No, because in virtually every context
11 I can think of, with a few exceptions in the
12 product safety area where it's clear a chain saw
13 causes an evulsion in a particular case, you're
14 dealing with a variety of unknowns that have also
15 been shown to be associated with the same
16 phenomenon. Therefore, I personally do not
17 believe that epidemiology by itself can lead to a
18 competent conclusion that a causal relationship
19 probably or is more likely to exist.

20 Q. But a body of epidemiological evidence
21 could move your judgment in that direction; that
22 is to say, in the direction of believing that a
23 cause-and-effect relationship probably exists?

24 MR. DUNCAN: Objection to form.

25 THE WITNESS: No. It would increase

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1 the likelihood of my belief that a causal
2 relationship may exist. But the whole premise of
3 epidemiology, when you're looking at data, is
4 that all else being equal.

5 And, with epidemiologic data, when
6 you're dealing with populations, you generally
7 don't have the precise measures you need on
8 everybody in that population to get to that
9 point.

10 BY MR. PICCIONI:

11 Q. So one epidemiological study with a
12 relative risk of 1.2 with a confidence interval
13 between 0.8 and 1.8 is as persuasive as 100
14 epidemiological studies with relative risks that
15 are never less than ten?

16 A. More persuasive in what?

17 Q. In your reaching an opinion that a
18 cause-and-effect relationship probably exists.

19 MR. DUNCAN: Objection as to form.

20 THE WITNESS: Again the premise here is
21 that I can be convinced that a cause/effect
22 relationship probably exists from a body of
23 epidemiologic data. And I'm trying to get across
24 to you the fact that epidemiologic data by
25 themselves, regardless of what the relative

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1 effects are and regardless of the number of
2 studies, convince me only that a causal
3 association may exist.

4 Until I can demonstrate that by knowing
5 what the confounders are and physically
6 controlling for those confounders, ruling them
7 out as potential causes within the population,
8 I'm no more convinced than I was before. I would
9 be convinced of the potential that a causal
10 relationship may exist only, not on the
11 probability.

12 BY MR. PICCIONI:

13 Q. But your conviction that the potential
14 exists might be stronger if the epidemiological
15 evidence was as I described in the second
16 example?

17 A. My conviction that a causal
18 relationship may exist would be stronger with
19 replication, yes.

20 Q. And strength of association?

21 A. And strength of association, but not
22 definitive.

23 Q. Am I correct in understanding that what
24 you need further beyond epidemiological results
25 is an understanding of mechanism?

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1 A. Yes. But that's not all I need.

2 Q. What else?

3 A. I would want epidemiological data that
4 demonstrates the presence or absence of the other
5 potential causes in that population and the
6 degree to which they are present.

7 Q. But that's epidemiological data, those
8 are epidemiological associations, correct?

9 A. That's true.

10 Q. Which are obtainable not just in
11 principle but in the real world?

12 A. For the most part, they are if you're
13 willing to spend the time and money to gather
14 them. But it also requires that you conduct your
15 study on the population of interest, not on a
16 surrogate population, unless you can assure that
17 the surrogate population is, in fact,
18 representative.

19 Q. If I'm confining myself to the
20 population upon which the epidemiological study
21 was actually conducted to a situation in which
22 the epidemiological evidence includes
23 investigation of potential confounders --

24 A. All known potential confounders and
25 suspected confounders.

1 Q. To be sure. And the association that
2 is observed is strong and any other indicia that
3 you would like to mention, all within the sphere
4 of epidemiological evidence, is it only mechanism
5 that is missing?

6 MR. DUNCAN: Objection as to form.

7 THE WITNESS: When you get to this
8 point, you're moving to that gray area between
9 epidemiology and clinical medicine that
10 accounts -- that is known as case control
11 studies, where you have the information on the
12 population, now you want to know how that applies
13 to the individuals within that population.

14 Then you have all the information you
15 need, you have the epidemiological information,
16 you have the clinical information on the
17 individuals and their individual exposure rates,
18 then you can make a positive determination.

19 But you are really into that gray area,
20 you're really having to go slightly beyond
21 epidemiology into clinical medicine, because
22 you've got to bring it down to the individuals or
23 some representative sample of those individuals
24 within that population for whom you are taking
25 actual measurements on those potential

1 confounders, be they exposure to other toxins in
2 the environment or habits that may also be
3 confounders or gene pools, if you've got the
4 genetic history or the medical history of the
5 individual families. All of those go into making
6 up the necessary body of data to make a
7 definitive statement about cause and effect.

8 BY MR. PICCIONI:

9 Q. Even a statement being made about
10 whether a cause-and-effect relationship is more
11 probably true than not true?

12 MR. DUNCAN: Objection as to form.

13 THE WITNESS: I'm not certain how to
14 answer that. If you have this body of
15 epidemiologic information on the precise target
16 population that you're looking at and on all of
17 the confounders, you could probably come down to
18 a statement of more likely true than not true or
19 probably true. But you would still have to check
20 it.

21 BY MR. PICCIONI:

22 Q. How can you ever be sure you know about
23 all the confounders?

24 A. Well, by reviewing the literature, you
25 can know about all known or potential confounders

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1 that have been identified. Then it simply
2 becomes a matter of finding a way to measure it.

3 Q. Can't someone always come up with
4 another potential confounder?

5 A. Conceivably, yes. That's a problem.
6 And that's why I said you really have to go
7 beyond epidemiology to be definitive.

8 Q. To be definitive or to render an
9 opinion that a cause-and-effect relationship is
10 more likely to exist than not?

11 A. Certainly to be definitive. It would
12 really be a judgment call in any case as to
13 whether or not you want to say more likely than
14 not at that point. I tend to err on the side of
15 conservative. I prefer to see things definitively
16 spelled out.

17 In population data you are dealing with
18 populations, groups of people. And not all of
19 them are going to react exactly the same to any
20 particular influence. We've just been alluding
21 to confounders in the sense of potential
22 causation so far or at least implicit in our
23 conversation. There are also confounders that
24 may be protective.

25 (Discussion off the record.)

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1 BY MR. PICCIONI:

2 Q. I'm handing you a copy of your expert
3 report in the Minnesota case. Does this report
4 bear some relation to the report that you
5 prepared in the Northwest Laborers case and the
6 Ohio case?

7 A. Well, not directly. I mean some of it
8 obviously is covering some of the same ground.

9 Q. On page 10 there is a section beginning
10 with the words less convincing. Do you see that?

11 A. Uh-huh.

12 Q. If you could look at your report in the
13 Ohio case, beginning at page 5. Sorry, beginning
14 at page 7. And the section on page 7, where it
15 starts with the heading Logical & Scientific
16 Flaws, we start with the words in public health
17 present in both reports.

18 If we look in the Ohio case, the second
19 to the last sentence there ends population to be
20 served. And, if we look in the Minnesota report,
21 we can also see text ending in the sentence
22 population to be served.

23 A. Sure.

24 Q. In the Ohio case, there is one more
25 sentence, and then the start of a new paragraph

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1 beginning in situations. In the Minnesota
2 report, there is a section --

3 MR. DUNCAN: Objection as to form. Are
4 these questions?

5 BY MR. PICCIONI:

6 Q. I'm implying, when I'm making these
7 statements, the question are you following me
8 when I'm pointing to each of these sections of
9 text. Is that clear?

10 A. I'm not quite sure where you're going
11 with this. I mean I plagiarize myself obviously,
12 I say I'm covering the same ground, in some cases
13 I've used some of the same structure I've used
14 before, in others I've added to it, I've modified
15 it, I've grown with it. I'm not sure what your
16 question is.

17 Q. In the Minnesota report, there is a
18 section beginning less convincing and running
19 through the end of that paragraph.

20 A. Okay.

21 Q. Is that language in your Ohio report?

22 A. It may be, it may be identical, it may
23 be slightly modified. Do you want me to read the
24 both of them and see?

25 Q. If you can take a minute or two.

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1 A. Sure. If I had some idea what your
2 question was going to be, I could read it with
3 that in mind.

4 Q. Why don't you see whether it's present
5 in the Ohio report.

6 A. The thrust of it is the same. I think
7 I added a little more. It's not identical. I'm
8 not sure, how far do you want me to read on
9 this?

10 Q. Am I wrong that the entire section
11 starting with the word too, t-o-o, too often --

12 A. I was starting at far less convincing.

13 Q. It's the next sentence.

14 A. Well, the next sentence in which one,
15 in the Minnesota?

16 Q. In the Minnesota.

17 A. All right. Too often, right.

18 Q. Am I correct that that entire section,
19 running from that sentence to the end of the
20 paragraph in the Minnesota report, is absent from
21 the Ohio Iron Workers report?

22 A. Yes, it appears to be.

23 Q. Do you remember deciding to delete that
24 section?

25 A. I don't remember specifically why or

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1 when I decided to delete it. What I usually did
2 was I read through previous reports to see what
3 was usable in the future, made notes to myself,
4 and then wrote, if possible, pretty much from
5 scratch.

6 Sometimes, if I covered things in a
7 slightly different context, I struck them out
8 completely in the earlier one. There's really
9 not a nefarious purpose to it, it's just that, in
10 trying to put the thing together as a coherent
11 whole, I wrote it the way I wrote it.

12 Q. I certainly wasn't suggesting the
13 purpose was nefarious, I was just trying to
14 understand.

15 A. Well, that's why I was wondering if I
16 could have some idea of what the question was, it
17 would have been helpful when I read through it
18 rather than having to go back then again and see,
19 because I was obviously misinterpreting what
20 sentence you were beginning with and so forth.

21 In any event they're related in the
22 sense that they cover some of the same ground.
23 They're unrelated in the sense that each one is
24 an independent report.

25 Q. Looking at that section that we

1 identified which was deleted from the Minnesota
2 report in creating the Northwest Laborers report
3 which was the progenitor of the Ohio report --

4 MR. DUNCAN: Objection as to form.

5 BY MR. PICCIONI:

6 Q. -- is there anything about the content
7 of these sentences that is not true any longer or
8 does not apply?

9 A. No.

10 Q. Is not true in the context of the Ohio
11 case?

12 A. No, I don't think so. I think I just
13 covered it in a somewhat different fashion,
14 that's all.

15 Q. Doctor, is it your understanding that
16 the National Medical Expenditure Survey database
17 is relied upon by any expert in this case as a
18 source of data on exposure or expenditures?

19 A. I think it's relied to in a sense. The
20 disease rates themselves come from the Surgeon
21 General's report. And the smoking data comes
22 from the Health Interview Survey. But the NMES
23 itself is not to my knowledge directly involved
24 in the computation. I'd have to go back and
25 check, but I don't think it is.

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1 Q. Would NMES have been a more reliable
2 source for information about exposure or
3 expenditures than the data relied upon by
4 plaintiffs' experts in this case?

5 A. I don't think it would be more
6 reliable. I think it has problems of its own,
7 that there are a number of difficulties when
8 you're dealing with national databases on
9 subunits of that national population. And I have
10 explored that to some extent in this report.

11 Q. This report meaning the Ohio report?

12 A. The Ohio report.

13 Q. Am I correct that it's explored to a
14 greater extent in the Minnesota report?

15 A. I don't think so. It may or may not
16 be. I talk about the synthetic estimation
17 process. It's not a minor problem, it's I
18 consider a major problem.

19 The amount of space I give to it is not
20 necessarily indicative of the importance compared
21 with something else that may have more space. It
22 probably has more to do with my ability to
23 articulate my argument when I was writing it.

24 Q. How about the problem of self reporting
25 of health status?

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1 A. No less important now than it ever
2 was.

3 Q. So it's important to the use of and
4 reliance upon NMES data?

5 A. That's correct. It's also important to
6 the use or reliance on Health Interview Survey
7 data.

8 Q. Would the problems in using NMES to
9 make reliable estimations of the relationship
10 between smoking history and expenditure be solved
11 by confining the analysis to a subset of the NMES
12 population?

13 A. No, for the reason that the NMES
14 population was a national population. If I could
15 put this in the context of the surveillance
16 system we had at CPSC which I developed, it was a
17 national sample. And we had hospital emergency
18 rooms reporting on a daily basis all
19 product-related injuries treated in their
20 emergency rooms.

21 Now, if the state of California which
22 had perhaps six hospitals in the system out of 91
23 total wanted to know anything about injury
24 problems in their state, we could not simply take
25 the California contingent of hospitals and draw

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1 any conclusions for California based upon those
2 because they were not designed as a statistical
3 subset of California hospitals. Each hospital in
4 the system was part of a national system.

5 But with NMES it was a national sample,
6 it was not designed to be used at the state or
7 lower level. Like most national systems, the
8 best you can do is bring it down to perhaps
9 region, one of the four census regions.

10 Q. Suppose you were to confine or someone
11 were to confine their analysis to those
12 participants in the NMES study who obtained their
13 health insurance from a union insurance fund.
14 Would that data be reliable as a source of
15 information on the relationship between smoking
16 and disease as it exists in trust funds in Ohio?

17 MR. DUNCAN: Objection to the form.

18 THE WITNESS: No, I do not believe they
19 would be.

20 BY MR. PICCIONI:

21 Q. How about if the population were
22 restricted to participants in the NMES study who
23 described their occupation as construction
24 workers. Would results obtained from such a
25 subpopulation of NMES provide a reliable basis

1 upon which to make statements about the
2 relationship between smoking and expenditures in
3 the Ohio Trust Funds?

4 A. I don't believe they would, no.
5 (Verhalen-Ohio Exhibit No. 2
6 was marked for identification.)

7 BY MR. PICCIONI:

8 Q. I'm handing you a couple of pages from
9 the 1989 Surgeon General's report, Chapter 3.
10 And I'd like you to look at table 6 at page 150.
11 Are you on that page?

12 A. I am.

13 Q. The last number in the second column,
14 the column headed Current Smokers?

15 A. Current Smokers.

16 Q. Yes.

17 A. Okay.

18 Q. Can you explain to me the relationship
19 between the number that's not in parentheses and
20 the numbers that are in parentheses?

21 A. The number not in parentheses is
22 essentially a mean value. The number in
23 parentheses is the 95 percent confidence interval
24 which means there is an equal likelihood it could
25 be at the lowest number or the highest number.

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1 Q. So, if we go over one column to the
2 right there and we see another estimate, another
3 set of numbers, a value 1.9 with a confidence
4 interval of 1.28 to 2.82?

5 A. Which one are we looking at now?

6 Q. Former smokers.

7 A. But which one are you looking at, the
8 bladder cancer?

9 Q. Yes, the last row. That's compared to
10 the previous value we were talking about which
11 was 2.86 with a confidence interval of 1.85 to
12 4.44. From a statistical point of view, are
13 those two means different?

14 A. I don't think they're identified as
15 statistically different. They may be. I'm not
16 sure how they're -- certainly there's a
17 difference.

18 Q. Terrible question. Is the difference
19 in the means of these two observations
20 statistically significant at the 95 percent
21 confidence level?

22 MR. DUNCAN: Objection as to form.

23 THE WITNESS: There's nothing here that
24 indicates it is a statistically significant
25 difference that I can see offhand. But the error

1 margins overlap considerably. So the likelihood
2 of statistical significance reduces
3 commensurately.

4 BY MR. PICCIONI:

5 Q. So, when you say the error margins
6 overlap considerably, you mean that's because the
7 lower limit of the value for current smokers,
8 1.85, is less than the upper limit for the value
9 for former smokers of 2.82?

10 A. Considerably less, yes.

11 Q. Is that a general principle of
12 statistical methodology, that two observed means
13 aren't statistically significantly different if
14 the lower limit of the confidence interval of the
15 higher value is less than the upper limit of the
16 confidence interval of the lower value?

17 MR. DUNCAN: Object to the form of the
18 question.

19 THE WITNESS: No, it's not a general
20 principle. It's sort of a rule of thumb that you
21 can use when you're glancing at things. You
22 subject them to a statistical test of
23 differences. There are any one of a variety of
24 tests that one could use.

25 BY MR. PICCIONI:

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1 Q. But, if someone were to come forward
2 and say that these two means are different, would
3 you be supportive or unsupportive of such an
4 assertion?

5 MR. DUNCAN: Objection as to form.

6 THE WITNESS: I don't think I would be
7 one way or the other. I would look at it and ask
8 myself whether or not I wanted to subject this to
9 a statistical test.

10 BY MR. PICCIONI:

11 Q. What kind of statistical test?

12 A. There are a variety of tests you could
13 use, you could use an analysis of variance, you
14 could use a student's T or a Z test, any one of a
15 variety of tests that may be applied. I am not a
16 statistician.

17 But a statistician has a number of
18 tools at his disposal, none of which are exactly
19 always correct. It's up to the judgment of the
20 statistician which one he wants to use. But I
21 would generally defer to a statistician.

22 Q. But it would be methodologically
23 problematic in your mind to conclude that there
24 is a difference between these two means absent
25 other information when the confidence intervals

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1 overlap; is that correct?

2 MR. DUNCAN: Object to the form.

3 THE WITNESS: No. I don't have a
4 problem with saying there's a difference between
5 the two means. I can see the difference, 2.86 to
6 1.90. The significance of that difference is
7 problematic only in the sense that there is not
8 an indication that they are statistically
9 different.

10 When there is no such indication, the
11 first thing that occurs to me is they are not
12 statistically significant, they are different.
13 And, when I see overlapping confidence intervals,
14 it enhances the notion that this really should be
15 subjected to a test for differences. The fact
16 that they didn't overlap wouldn't necessarily
17 lead me to not bother with wanting a test, I
18 would still want a test.

19 Q. Doctor, what part of the CPS II study
20 is based on self reporting?

21 A. Actually it's really all based on self
22 reporting because people are drawn into the
23 system by volunteers who then interview them.
24 And what they're getting is all the information
25 they gathered was gathered from the individuals,

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1 it was not gathered from a third source, any
2 administrative records or anything of that
3 nature.

4 Q. Cause of death was determined -- was
5 self reported?

6 A. Well, certainly was self reported
7 initially because nobody had a record of their
8 death until the next cycle of the interview and
9 they said, well, Sam died, and then they were
10 able to get a hold of the record if they required
11 it. I don't know that they did.

12 Q. You don't know whether cause of death
13 in CPS II was determined from looking at death
14 certificates; am I correct?

15 A. Ultimately the cause of death that was
16 recorded was from the death certificate. But the
17 initial indication of the fact of death was on
18 the part of the self reporting.

19 Q. Do you know if the death certificates
20 in the CPS II study were reviewed for errors?

21 A. I don't personally know, but I doubt
22 that they were, because that would have required
23 going back to the medical records to look. In
24 most cases what we were dealing with is not the
25 deaths but morbidity rather than mortality.

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1 Deaths were certainly a part of the CPS
2 II study, but there was -- a large part of CPS II
3 was dealing with morbidity situations, people who
4 had disease conditions that they reported to the
5 interviewer.

6 Q. We're talking about the Cancer
7 Prevention Study part II?

8 A. Yes, that's correct.

9 Q. Conducted by the American Cancer
10 Society?

11 A. That's correct.

12 Q. What is or are the documents that
13 describe that study that you looked to for
14 information about it?

15 A. I had a series of documents that were
16 the original questionnaires that were used by the
17 interviewers in CPS II which I had gotten on my
18 own request from Shook, Hardy & Bacon. But my
19 concern was not with the accuracy of the data so
20 much as with the precision of the data. I'm
21 sorry, the representation of the data.

22 I do have a concern with CPS II as it
23 relates to the use of the ICD-9 codes because
24 ICD-9 coding is always subject to clerical
25 error. These codes, whether they're taken to the

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1 first, second, or third decimal place, can get
2 fairly complex. And clerical errors are common.

3 Q. Do you still have these documents that
4 you obtained?

5 A. I probably do. I haven't seen them in
6 sometime, but they're probably somewhere around
7 the office.

8 Q. And they form in part a basis for your
9 opinions about the CPS II study?

10 A. Well, certainly they -- yeah, they must
11 have. I looked at them fairly early on, long
12 before we got into this. So, for whatever
13 knowledge I have on CPS II, that's where it would
14 come from.

15 Q. And it would be possible to locate
16 those documents and make copies of them?

17 A. Certainly.

18 MR. PICCIONI: I'd like to request that
19 we do so.

20 MR. DUNCAN: Is there a notice and
21 request for documents in conjunction with this
22 deposition, do you know?

23 MR. PICCIONI: My understanding is
24 there is an agreement.

25 MR. DUNCAN: Okay.

1 MR. PICCIONI: To produce documents
2 which are not published upon which the witness
3 relies as a basis for his testimony.

4 (Discussion off the record.)

5 (Verhalen-Ohio Exhibit No. 3
6 was marked for identification.)

7 BY MR. PICCIONI:

8 Q. Doctor, I'm handing you a copy of an
9 article I've had marked as an exhibit. The
10 authors are Percy, et al. Is this one of the
11 articles that you list among the references in
12 the back of your report in the Ohio case?

13 A. I think so. Yes.

14 Q. Am I correct that you cite this article
15 as providing support for the proposition that
16 miscoding of ICD-9's as the underlying cause of
17 death could be a source of error in the CPS II
18 study?

19 A. As one of the arguments, yes.

20 Q. Does this study by Percy, et al.,
21 present data from participants in the CPS II
22 study?

23 A. No, I don't believe it does. It simply
24 uses Third National Cancer Survey. And it seems
25 to me this is an NIH. Yes.

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1 Q. Is it from a period of time that
2 overlaps the study period of the CPS II?

3 A. No. Really it's between CPS I and CPS
4 II.

5 Q. Is it the same -- strike that.
6 Does the population studied in this
7 paper have the same age structure as the CPS II
8 study population?

9 A. I didn't review with that in mind.
10 That was not the point of the citation. The
11 point of the citation was the accuracy of the ICD
12 codes.

13 Q. But am I wrong in concluding that you
14 believe that this research described in this
15 study is applicable in some sense to potential
16 problems in the CPS II study?

17 A. Methodologically, yes.

18 Q. If you look at table 3 on page 246 of
19 The Percy report, and we look at the row that's
20 labeled 162 for the ICD-8 category, so they're
21 using here ICD-8 versus ICD-9 in CPS II; am I
22 correct?

23 A. That's correct.

24 Q. But the results of this study are,
25 nevertheless, useful in considering potential

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1 methodological problems in CPS II, correct?

2 A. Yes. The ICD coding itself is what the
3 focus is in this article. ICD-7 was used in the
4 first CPS study, ICD-8, and then ICD-9 was used
5 in the last study. ICD-10 has just been
6 published.

7 Q. Going back to the line that begins at
8 162, in the second numerical column, am I correct
9 that that is a count of the number of cases in
10 which lung cancer was listed as the cause of
11 death on the death certificate?

12 A. That's correct.

13 Q. And the preceding column is the number
14 of cases in which lung cancer was listed as the
15 cause of death based on the hospital records?

16 A. Well, that was the diagnosis in the
17 hospital.

18 Q. Thank you. So that I could obtain the
19 number of times that the cause of death on the
20 death certificate was listed as lung cancer when
21 the hospital diagnosis was not lung cancer by
22 taking the difference between the second column
23 and the first column; is that correct?

24 MR. DUNCAN: Objection as to form.

25 THE WITNESS: I think that's correct,

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1 yes.

2 BY MR. PICCIONI:

3 Q. Now, can you do that arithmetic for me?

4 A. You mean the -- the 10,059 from the
5 178?

6 Q. Yes.

7 A. It's 118 -- 19.

8 Q. Excuse me. So it's 119 cases out of
9 how many?

10 A. Out of roughly 10,000.

11 Q. If we look at table 2 on page 244 and
12 go down to the row that starts lung plus and then
13 the next column is 162, am I correct that
14 skipping the next column which has the value
15 10,059 and adding up the numbers in each
16 subsequent column up to 161, the column labeled
17 161, and then continuing the addition with the
18 column labeled 160 to 163, proceeding all the way
19 across the page, I'll get the total number of
20 cases in which the hospital diagnosis was lung
21 cancer, but the underlying cause of death listed
22 on the death certificate was not lung cancer?

23 A. As long as you leave out column 162,
24 that's correct.

25 Q. If I add up those numbers and they are

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1 greater than the difference between 10,178 and
2 10,059, am I right in concluding that the
3 apparent errors in the coding of cause of death
4 for lung cancer led to fewer cases of lung cancer
5 identified as the cause of death on the death
6 certificate than if those apparent errors had not
7 been made?

8 A. No. Of the 10,059 diagnosed within the
9 hospital, 9,560 were actual lung cancer or at
10 least appeared on the death certificate. But
11 remember that, if you go down 163, column 163,
12 you've got a number of cases that appeared on the
13 death certificate as lung cancer which were not,
14 the hospital diagnosis was something other than
15 lung cancer.

16 Q. Do you mean column 162?

17 A. Yes. I'm sorry. Yes, 162. My finger
18 slipped over one. If you go down column 162, you
19 find that 22 cases, for example, that appeared on
20 the death certificate as lung cancer were
21 actually diagnosed in the hospital as buccal
22 cavity cancer, 13 were esophageal, ten were
23 stomach, 25 were colon, nine were rectum,
24 et cetera. You have to look at this in both
25 directions.

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1 MR. DUNCAN: Would this be a good place
2 to break?

3 MR. PICCIONI: Just one minute.

4 BY MR. PICCIONI:

5 Q. On table 3 there's a column entitled
6 Confirmation Rate. What's your understanding as
7 to what that value is that's presented?

8 A. That 93 percent of the death
9 certificates labeled as 162 were actually 162.

10 Q. Actually meaning according to the
11 hospital?

12 A. Had been diagnosed in the hospital as
13 162.

14 Q. And the column to the left of that is
15 the Detection Rate. What's your interpretation
16 of the meaning of that value?

17 A. I hadn't really looked at detection
18 rate. I don't know, I would have to go back into
19 the article.

20 Q. Okay. Could it be that that is the
21 percentage of cases in which the hospital
22 diagnosis was lung cancer and the cause of death
23 listed on the death certificate was also lung
24 cancer?

25 MR. DUNCAN: Objection, asked and

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1 answered.

2 THE WITNESS: I can read you the
3 definition from the text. "The detection rate
4 for a specific site was defined as the number of
5 cases diagnosed as cancer of that site in the
6 hospital and having cancer of the same site on
7 the death certificate divided by the total number
8 of persons diagnosed with that specific site of
9 cancer in the hospital and dying of cancer. It
10 is, therefore, the proportion of hospital
11 diagnoses with cancer of a certain site in which
12 the cause of death reflects the same hospital
13 diagnosis."

14 MR. PICCIONI: Why don't we go ahead
15 and have some lunch.

16 (Whereupon, at 1:05 p.m., the
17 deposition in the above-entitled matter was
18 recessed, to reconvene at 1:50 p.m., this same
19 day.)
20
21
22
23
24
25

AFTERNOON SESSION

(2:00 p.m.)

Whereupon,

ROBERT D. VERHALEN,

the witness on the stand at the time of recess,
having been previously duly sworn, was further
examined and testified as follows:

EXAMINATION BY COUNSEL

FOR PLAINTIFFS (RESUMED)

BY MR. PICCIONI:

Q. Doctor, if you can look at Exhibit 1
which I believe is your report in the Ohio case,
and at page 10, actually starting on page 9, the
very last sentence that begins on that page and
continues over to the next one, I'm having a
little trouble understanding those two
sentences.

The first sentence and the second
sentence of that paragraph, are they both
supposed to be there; that is, are they saying
something different as opposed to saying just the
same thing twice?

A. No. I think the second sentence is
simply explaining the first sentence.

Q. Okay.

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1 A. And I'm not always the most efficient
2 writer.

3 Q. So the reference standard, if you will,
4 that's here, am I correct that it's a reasonable
5 level of epidemiological certainty?

6 A. That the information is correct.

7 Q. Can you tell me more about what you
8 mean by a reasonable level of epidemiological
9 certainty?

10 A. Well, something beyond the 60 percent
11 that's alluded to in the Bright article, probably
12 up in the neighborhood of 90, 95 percent would be
13 comfortable. It's to that that I also address
14 myself to the fact that, if you've got a large
15 population, you might be better off taking a good
16 statistical sample rather than trying to do
17 100 percent as a census.

18 Q. The 90, 95 percent value you just cited
19 refers to what exactly?

20 A. Concordance between reality and what
21 was on the code, if you were to check the medical
22 record to ensure that it and the ICD-9 code refer
23 to the same disease condition.

24 Q. And that value determined to what level
25 of precision?

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1 A. I don't follow your question there.

2 Q. You speak here about the possibility of
3 using statistical sampling, am I correct, in
4 estimating that concordance value?

5 A. Oh, I think that it would be reasonable
6 to probably set that at the 95 percent level;
7 that, if you take a sample that would give you an
8 estimate within 5 percent of the true figure, at
9 the 95 percent confidence level, that I would
10 probably be comfortable with that, that the
11 information is sufficiently accurate to be used.

12 I mean these are values that would have
13 to be determined as you're going into it.
14 Certainly any competent statistician could design
15 a study that would provide that or a sample that
16 would provide that.

17 Q. So that, if I understand this
18 correctly, and correct me if I don't, the
19 estimate that came out of this analysis was that
20 there was a 95 percent concordance. And that
21 estimate ranged between 90 percent and
22 100 percent in the 95 percent confidence
23 interval?

24 A. Yeah. Actually the higher the better.
25 I have not thought through exactly what the

1 sample design should be or the level. But 60
2 percent is clearly too low. And you've got to do
3 something.

4 That suggests to me that the data
5 should be cleaned up; in other words, amended;
6 that, as you go through the data and you find
7 discordance, that it would be corrected to
8 whatever the diagnosis should have been and will
9 not be subject to random clerical error or any
10 other kind of clerical error.

11 Q. Are you saying that the concordance
12 rate in this population was 60 percent?

13 A. In the Ohio population?

14 Q. Yes.

15 A. No, I'm not. I don't know what it is.
16 But I venture neither do your own analysts.

17 Q. That's the figure that appears in the
18 Bright paper?

19 A. That's correct. They have found in
20 their review that there was an accuracy level of
21 60 percent.

22 Q. Which is --

23 A. I'm sorry, inaccuracy level of 60
24 percent.

25 Q. And that was a study of what kinds of

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1 populations?

2 A. That was Medicaid claims data that they
3 had reviewed. I offhand don't recall which
4 state, I would have to look at the paper again.

5 Q. Have you formed any opinions about the
6 necessary segregation of subpopulations within
7 the Ohio Trust Fund beneficiary population that
8 would have to be sampled separately?

9 A. Oh, I think each group would have to be
10 sampled separately because each comprises a
11 different population which may have systematic
12 differences from another, especially in terms of
13 their use of the medical benefits available to
14 them.

15 Q. By each group you mean each trust fund?

16 A. Yes. I don't have a list here of what
17 they are, there are five or six trust funds I
18 think.

19 Q. Within each trust fund, would men need
20 to be analyzed separately from women?

21 A. No. I think you can take a statistical
22 sample of that population. And, as long as it is
23 representative of the mix by age and sex, that
24 would be adequate. Again I would leave that to
25 the statisticians.

1 Q. And that also pertains to the issue of
2 what the diagnosis was or the putative diagnosis
3 was, also that you would not need to separately
4 analyze subgroups with different diagnoses?

5 A. I would think not, because we're not
6 talking here about systematic errors as a
7 function of diagnosis. We may be, but that's not
8 what I was driving at here.

9 I was driving principally here at just
10 clerical error which in themselves are
11 problematic. If there's a potential or any
12 suggestion that there is a systematic error
13 introduced by problems of definition, then that
14 raises another question. But I hadn't raised
15 that question.

16 Q. You're concerned about simply random
17 miscoding?

18 A. It may be random. If you could be
19 assured that it was purely random, then perhaps
20 it's not so bad, everything would wash out. But
21 there's no way to know that it's random. It may
22 be a function of the breadth of the code, some
23 ICD codes are broader than others.

24 Q. Do you have any opinion about the size
25 of the sample that would have to be taken?

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1 A. No, I don't.

2 Q. Do you have an opinion about whether
3 the information that you would be seeking could
4 be obtained from the medical records as opposed
5 to examination of the recipients themselves?

6 A. No, I don't, except in the instance
7 where there may not have been a physician's
8 diagnosis, I don't know that that would fit
9 here. But, if someone were making a claim absent
10 a physician's diagnosis, then you certainly would
11 want to know if that individual was properly
12 characterizing his condition. I expect that's a
13 much less frequent kind of problem, but it should
14 certainly be looked at.

15 Q. Why is it that a random sample across
16 these subpopulations of men and women, different
17 age categories, different diagnostic categories,
18 would be adequate; but a random sample across
19 those categories and funds would not be?

20 A. I'm not sure I understand the
21 question. Why is it that a random sample across
22 men and women overall would not be adequate,
23 whereas a random sample of men and women within a
24 fund would be, is that what your question is?

25 Q. Not exactly. You said, if I recall

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1 correctly, that you thought each fund would have
2 to be analyzed separately; but that within each
3 fund the men would not have to be analyzed
4 separately from the women, a random sample of the
5 total population within the fund would be good
6 enough.

7 A. Okay. That's pretty much -- I can't
8 say it really wouldn't be adequate. I don't know
9 that it wouldn't be adequate. It would depend on
10 the degree to which the population covered by any
11 particular fund is suitably representative of --
12 the population were fundamentally the same as the
13 population in the other funds.

14 If you have a fund which is made up of
15 predominantly more educated white collar type of
16 people associated with the union as opposed to
17 those who are perhaps less educated, working in
18 the field, then they constitute quite different
19 populations. And it would probably be best to at
20 least discriminate between those two kinds of
21 funds, because you have fundamental differences
22 in the types of individuals who make up the
23 population group.

24 Q. But you haven't been asked, Doctor, to
25 develop such a method?

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1 A. No, I have not.

2 Q. Do you have an opinion, if necessary in
3 the context of parameters that we might be able
4 to specify, about the magnitude of such an
5 undertaking?

6 MR. DUNCAN: Objection as to form.

7 BY MR. PICCIONI:

8 Q. Let me clarify. Magnitude would be
9 basically dimensions of time and dollars.

10 A. I don't have a formed opinion. I do
11 know that it would take some time and resources.
12 But I don't have an opinion as to whether we're
13 talking about days or weeks. But I don't think
14 it should be much more than that as a dedicated
15 effort.

16 Q. You've had experience obtaining medical
17 records from healthcare providers and conducting
18 examinations of individual people?

19 A. I have -- I have had experience getting
20 records from medical care providers and directly
21 from people, yes, when we've interviewed people
22 as well, yes.

23 Q. And what do you have in mind as a
24 number, if you do have one, of these individual
25 investigations that would have to take place when

1 you say it would be days or weeks, not months?

2 A. I don't have an idea of numbers. But,
3 if you've got data available and you were to go
4 to a sample, if the size of the population were
5 simply too large to do a census and you went to a
6 sample, you could draw a sample that would
7 probably be in the hundreds per unit and allow
8 you then to base some estimates and corrections.

9 But it would pretty much depend on how
10 large the errors were and where those errors
11 were. It's kind of feeling your way. But a
12 dedicated effort I think would be unlikely to be
13 months. It may be, but I just don't think it
14 would be. We did it at CPSC on more than one
15 occasion within less than six weeks and we were
16 dealing nationwide.

17 Q. How many individuals were part of the
18 study?

19 A. We probably -- I'm trying to think back
20 of what our first study was back in the late
21 seventies. It was probably close to 60 or 65,000
22 individuals that were actually contacted.

23 Q. Any idea of the cost of that study?

24 A. Yeah, I think back then it was around
25 50 to \$60,000. So you might say 100 to \$150,000

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1 today. I'm guessing, I'm not really in a
2 position without sitting down and trying to cost
3 it out what it would involve.

4 Q. One dollar or two per subject?

5 A. It depends on the ability to get at the
6 records and who you've got doing it and how much
7 you have to move people around. I'm really --
8 I'm really not in a position to make a competent
9 estimate for that. If somebody were to ask me to
10 do the study, I would have to sit down and cost
11 it out. It would probably take me a day or so to
12 cost it out.

13 Q. Doctor, in your Ohio report, page 4,
14 maybe you can help me here. Somewhere in your
15 report you make the statement or something like
16 the following statement, that it's unsound to
17 attribute to smoking diseases that are only
18 aggravated by smoking?

19 A. Yes. On reflection -- let's see here.
20 Here it is, the third bullet point from the
21 bottom. Mr. Roberts had suggested including
22 estimates of cost for treating conditions
23 aggravated by smoking rather than just conditions
24 that were caused by smoking. But I'm not quite
25 sure where in the document that was, I'd have to

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1 go back and review it.

2 Q. Could you give me an example of a
3 disease that would be like that?

4 A. Asthma conditions, for example, which
5 drove an asthma sufferer back to a physician for
6 additional treatment, for example.

7 Q. So suppose you have two populations of
8 asthmatics. One population smokes, the other
9 doesn't smoke. And suppose that, in the smoking
10 asthmatic population, there are more visits to
11 the doctor for the treatment of asthma. That is
12 not caused by smoking?

13 A. It may or may not be. There are a lot
14 of other conditions that go along with smoking
15 within families, indoor air pollution itself is
16 an aggravating condition and smoking exacerbates
17 that.

18 How much of an asthmatic sufferer's
19 additional suffering is due to smoking, how much
20 of it is due to indoor air pollution partly as a
21 result of smoking, partly as a result of
22 otherwise pollutants within the internal
23 atmosphere, it's just something that would
24 require a separate treatment I think if you were
25 to try to get into that and actually document

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1 what proportion of the seeking of treatment is
2 actually due to the aggravated condition as
3 opposed to the condition as it would have been
4 had there not been a smoker in the home for an
5 individual.

6 I mean just taking classes of treatment
7 for people, asthmatic sufferers, is not in itself
8 sufficient to know that, anymore than it is to
9 judge the occurrence of asthma to smoking.

10 Q. But, if you are comparing like
11 populations with regard to any other relevant
12 exposures or predisposition, the only difference
13 then being smoking, why wouldn't the difference
14 be attributable to smoking?

15 A. Because you've got someone who is
16 already under treatment for a particular
17 condition. And they may go to that condition --
18 go to their physician for treatment more often
19 for a variety of reasons other than due to the
20 actual exacerbating effects of smoke itself
21 simply because they're not feeling well. They
22 may have a completely different way in which they
23 relate to the healthcare system.

24 You cannot easily separate out the
25 portion of whichever kind of treatment they would

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1 seek which was a direct result of smoking for
2 these individuals. And, therefore, I think it's
3 silly to try to add that on.

4 Q. But, if the two populations are the
5 same in every respect except for the smoking and
6 the smoking population has more visits to the
7 doctor --

8 MR. DUNCAN: Objection, asked and
9 answered.

10 BY MR. PICCIONI:

11 Q. -- how could the difference not be
12 attributable to smoking?

13 A. As I said it may be more a function of
14 just general comfort level than it is actual
15 exacerbation of the condition. It doesn't
16 necessarily mean the condition is made worse.
17 But the individual may be more apt to go off to a
18 physician simply because he finds his environment
19 less pleasant and he's seeking treatment.

20 Q. In my hypothetical is it true that but
21 for smoking in my hypothetical as you understand
22 it, is it true that but for smoking the
23 expenditures of the two populations would be the
24 same?

25 A. They might be, yes.

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1 Q. In the hypothetical situation where but
2 for smoking the expenditures of the two asthmatic
3 populations would be the same, is the difference
4 between the expenditures of the smoking
5 population and the nonsmoking population
6 attributable to smoking?

7 A. It may be. But again I can only say
8 that there are -- when people are suffering
9 various levels of discomfort, if there are more
10 among them who will have a proclivity to seek
11 treatment that is not necessary simply to ease
12 their comfort level, not because the condition
13 itself has necessarily worsened, but simply as a
14 matter of course to -- it's like people who go to
15 the physician when they don't need to just
16 because it sets their mind at ease.

17 We're talking about conditions that are
18 not necessarily caused by but simply make the
19 individual less comfortable. It doesn't
20 necessarily require medical treatment, but he
21 seeks medical treatment.

22 Q. In the example that you're giving, it's
23 the smoking that makes the individual less
24 comfortable?

25 A. Yes. Let me put it in a different

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1 context.

2 Q. Well, actually I would prefer if you
3 just sort of answered the question at this
4 point.

5 MR. DUNCAN: Objection, that question
6 has been asked and answered several times.

7 BY MR. PICCIONI:

8 Q. You can answer.

9 A. Give me your question again.

10 Q. The question is whether the condition
11 that you were speaking to as causing people
12 discomfort which led them to go to the doctor
13 more often, are you talking about smoking as
14 being that condition which causes them to go to
15 the doctor more often?

16 A. It could be. The context in which you
17 put your question to me was whether or not, if
18 smoking -- if asthmatics in smoking households
19 had a higher medical cost for treatment of their
20 condition than those in nonsmoking environments,
21 would that be attributable to tobacco. Did I
22 understand your question correctly?

23 Q. That's close enough.

24 A. It may be associated with the smoking.
25 However, whether or not they actually require

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1 treatment because of the additional discomfort is
2 an open question. Frequently people will go to
3 treatment simply to ease discomfort which doesn't
4 necessarily require medical treatment, they just
5 feel more comfortable by having received it. And
6 that's why I wanted to try to put it in a
7 slightly different context for you.

8 Q. Are you saying that the only time
9 higher expenditures in smoking -- excuse me,
10 higher expenditures for a smoking population
11 compared to a nonsmoking population can be
12 attributable to smoking is if smoking is the only
13 cause of the higher expenditures?

14 A. Close. I have to put it in a slightly
15 different context in order to make clear what I
16 mean. If you have fraud in a system, for
17 example, and there is an extra amount of
18 treatment that is sought due to fraud and that
19 fraud is related in some way to smoking, I would
20 not consider that a legitimate smoking-related
21 cost because it's fraudulent. It's, nonetheless,
22 a cost of treatment.

23 Now, I'm not suggesting that an
24 asthmatic who is uncomfortable is fraudulently
25 seeking treatment. What I'm saying is that

1 they're seeking treatment at a higher rate, quite
2 possibly unnecessarily, and is that -- in my mind
3 that is probably not a legitimate
4 cigarette-related cost. Does that clarify it at
5 all for you?

6 Q. Even in the hypothetical absence of
7 smoking, all other things remaining constant,
8 those costs would be lower?

9 A. Yes. My hypothetical to your
10 hypothetical added on the notion of someone
11 seeking treatment fraudulently, for example.
12 And, if someone is seeking treatment that is not
13 necessary, simply because of some extra
14 discomfort, whether it's itchy skin or just a
15 general malaise, that to my mind is not a
16 legitimate cigarette-related cost that you can
17 fractionate out and say that is caused by
18 smoking.

19 It may be caused by a number of things,
20 smoking being only one of them. There's no way
21 to really know what portion of that is due to
22 smoking, even though there's a distinct
23 difference between a smoking population and a
24 nonsmoking population. There may be other
25 differences in those households between

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1 nonsmoking and smoking households that account
2 for that additional discomfort.

3 Q. Confining our discussion here to
4 disease incidence in persons who are themselves
5 smokers and to the list of the diseases in what I
6 imagine is Exhibit 2, at page 150 --

7 A. What are we talking about, are we
8 talking about the Surgeon General's report?

9 Q. Yes.

10 A. I think you took that away from me.

11 Q. Can you indicate to me given those
12 constraints which of these diseases you're
13 referring to as being aggravated by rather than
14 caused by smoking?

15 MR. DUNCAN: Objection as to form.

16 THE WITNESS: Certainly in the other
17 respiratory disease category and possibly in the
18 other heart disease category with respect to
19 something like congestive heart failure.

20 BY MR. PICCIONI:

21 Q. So that's not true, for example, about
22 lung cancer?

23 A. In all likelihood not.

24 Q. Why is that, why is it not?

25 A. Because, when people are under

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1 treatment for lung cancer, they're under
2 treatment for lung cancer. In most cases they're
3 not seeking medical treatment simply because
4 their anxiety level happens to be a little
5 higher. They've already been diagnosed.

6 I'm talking about conditions that
7 people can live a long time with such as
8 congestive heart failure and asthma and perhaps a
9 variety, chronic pleurisy, things of that nature.

10 Q. Let's say, for example, coronary heart
11 disease. And, considering research which
12 indicates to some people that the incidence of
13 coronary heart disease in a population is
14 associated with a variety of different risk
15 factors, are you saying that, if smoking
16 interacts with those other risk factors, the
17 excess number of cases observed in smoking
18 populations versus nonsmoking populations is not
19 attributable to smoking?

20 A. No, because here you're talking about
21 what constitutes putatively diseases that are
22 caused by smoking. I'm talking here about
23 diseases that are only aggravated by smoking but
24 that are not caused by smoking or not reputed to
25 be caused by smoking.

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1 Q. If you have a population of people who
2 are exposed to asbestos and you subdivide that
3 population into two halves, the half that smokes
4 and the half that doesn't by some definition of
5 smoking, and you observe a higher mortality from
6 lung cancer among the smoking asbestos workers in
7 comparison to the nonsmoking asbestos workers, is
8 that an example of a situation in which you would
9 say that smoking is aggravating a condition
10 rather than causing it?

11 A. No, that's not what I was getting at
12 here. I was getting at conditions which are not
13 normally by themselves considered terminal,
14 conditions that tend more to be chronic and cause
15 some degree of suffering, but not necessarily
16 conditions such as lung cancer brought on by
17 asbestos or asbestosis itself being aggravated by
18 this, where you've got a terminal condition.

19 I was talking about more the minor
20 conditions. Not that congestive heart failure is
21 necessarily minor, but it is much less
22 problematic than other heart conditions one can
23 suffer.

24 (Recess.)

25 MR. PICCIONI: Back on the record.

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1 BY MR. PICCIONI:

2 Q. Doctor, we were talking about product
3 safety. I asked you whether you could think of
4 products that were in some respects less safe now
5 than they were 25 years ago. Do you recall those
6 questions?

7 A. Yes.

8 Q. If we confine the question to products
9 that are used in the same way as they were 25
10 years ago, can you give me some examples of
11 products that are less safe than they were 25
12 years ago?

13 A. Not off the top of my head. With
14 reflection I might be able to.

15 Q. Can you give me examples besides chain
16 saws of products that are safer now than they
17 were 25 years ago in that same sense, with the
18 same use, pattern of use?

19 A. Yes. I think infant cribs would be a
20 good example.

21 Q. Automobiles?

22 A. With automobiles we've kind of traded a
23 headache for an upset stomach. I'm not sure that
24 they're all that much safer. We have a lot of
25 safety devices in them, but people still seem to

1 be able to get themselves into trouble. And I
2 think the recent emergence of air bag injuries to
3 small children is a reasonable example of a
4 safety feature that wasn't necessarily safe for
5 everybody.

6 Q. But on balance an improvement in safety
7 or a detriment to safety, the air bag?

8 A. On balance an improvement.

9 Q. Pharmaceutical drugs?

10 A. I don't know much about pharmaceutical
11 drugs.

12 Q. What do national statistics suggest
13 about the per capita occurrence of injuries
14 caused by products show in terms of a trend over
15 time, over the last 25 years?

16 MR. DUNCAN: Objection as to form.

17 THE WITNESS: Deaths?

18 BY MR. PICCIONI:

19 Q. We could look at deaths, sure.

20 A. A reduction in deaths - one has to be
21 very careful in looking at the data with a broad
22 array of things such as products because
23 different exposures have different ways of
24 measuring them.

25 But, if you just talk about crude

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1 numbers per product out there, there's been some
2 reduction in deaths. But that's more a function
3 of better treatment than it is necessarily safer
4 products, because new products are coming on the
5 market constantly.

6 Q. Same question but as to injuries?

7 A. Probably pretty much the same as it
8 was. Injuries have moved since the turn of the
9 century from seventh leading -- well, this is
10 deaths. But seventh leading cause of death to
11 fourth. But that's because others have
12 increased. Injuries have been roughly 30 million
13 a year. Hospital emergency room treated injuries
14 for the last 20 years hasn't shown any real
15 strong trend upwards or downwards.

16 Q. That's with an increase in the
17 population?

18 A. That's with an increase in the
19 population. But over 20 years the increase
20 hasn't been that substantial. You're talking
21 about between 28 and 33 million injuries a year.
22 And injuries are distributed kind of randomly in
23 the population. So it's a little difficult to
24 really pin it down.

25 Q. So are you saying that it's the rare

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1 instance to find a product for which design
2 changes over the past 25 years have improved
3 safety?

4 MR. DUNCAN: Objection as to form.

5 THE WITNESS: That's not what I said.
6 I think that improving safety for individual
7 products has been a goal and probably an
8 achievement of many in the field. But there are
9 new products coming out on the market constantly
10 that simply regenerate a whole new generation of
11 accidents.

12 BY MR. PICCIONI:

13 Q. So, as to products that existed before
14 and still exist now, it is an achievement in the
15 field?

16 MR. DUNCAN: Objection as to form.

17 THE WITNESS: Yes, I would say it is.

18 BY MR. PICCIONI:

19 Q. Doctor, is it your opinion that there
20 is no safe level of lead in paint?

21 MR. DUNCAN: Objection as foundation.

22 THE WITNESS: It's my opinion that you
23 cannot identify a level of lead in paint that is
24 safe, that's correct.

25 BY MR. PICCIONI:

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1 Q. Just to address counsel's objection, if
2 you can refer to your report in the Minnesota
3 case, at pages 14 and 15, am I correct that
4 you're giving as an example of something an
5 episode involving the setting of permissible
6 levels of lead in paint?

7 A. That's correct.

8 Q. That's a section that is not in the
9 Ohio report; is that correct?

10 A. It probably isn't. I think I dropped
11 that out after the first two or three reports.
12 It's, nonetheless, true.

13 Q. Are there other reports besides the
14 Minnesota, the Washington Laborers case, and the
15 Ohio Iron Workers case?

16 MR. DUNCAN: Objection as to form.

17 THE WITNESS: I'm trying to remember if
18 we did a report for Texas. I think we did a
19 report for Texas.

20 BY MR. PICCIONI:

21 Q. So you understood my question to refer
22 to reports prepared under your direction and as
23 part of your participation as an expert witness?

24 A. Yes.

25 MR. PICCIONI: We'd like that report

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1 produced, if possible.

2 MR. DUNCAN: Was that part of the
3 agreement, do you recall?

4 MR. PICCIONI: Good question.

5 BY MR. PICCIONI:

6 Q. Is there a sense in which you rely upon
7 any research or investigation performed for the
8 creation of the Texas report in your report
9 submitted in Ohio?

10 A. No. Do you mean separate research?

11 Q. In other words, is there any effort
12 that was expended on your part in producing the
13 Texas report that also contributed to the
14 creation of your report in Ohio?

15 MR. DUNCAN: Objection as to form.

16 THE WITNESS: I really -- each report
17 built on the previous reports to the extent there
18 were common areas of concern. It depends on what
19 the model was that was being used. But it was
20 not separate research, it was separate review of
21 documents and statements made with reference to
22 those documents.

23 BY MR. PICCIONI:

24 Q. So, to the extent there were common
25 areas of concern, the Ohio report built on the

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1 Texas report?

2 A. It was built from the same -- the
3 review of much of the same material as the Texas
4 report. Was there a separate report? I really
5 can't recall which one we actually did a written
6 report for. I don't know if Texas did a summary
7 or Mississippi did a summary, but it was one of
8 those two. That was a year or so ago, it's tough
9 to remember.

10 Q. But prior to the Ohio report?

11 A. Yes.

12 Q. Doctor, you make the statement
13 somewhere in your report I believe, correct me if
14 I'm wrong, that CPS II was not intended to be
15 applied to populations below the national level;
16 is that correct?

17 A. That's correct.

18 Q. Has it been applied to populations
19 below the national level other than in the
20 context of either the Northwest Laborers case,
21 the Ohio Iron Workers case, any of the Attorney
22 General's Medicaid reimbursement cases?

23 A. To the best of my knowledge, no. It
24 may have been, but I don't know.

25 Q. Are you familiar with the SAMMEC

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1 program developed by the Centers for Disease
2 Control?

3 A. Yes.

4 Q. Is it your understanding that one of
5 the purposes of that program was to enable
6 subnational entities to develop their own
7 estimates of smoking attributable mortality?

8 A. Yes.

9 Q. And does that component of SAMMEC rely
10 upon the data obtained from the CPS II study?

11 A. I think, to the extent that it
12 documents the need through use of the Surgeon
13 General's report which is national data, yes.
14 I'm trying to remember back whether or not they
15 tried to take those figures and plug them in
16 directly. I don't think they do.

17 Q. Well, let's just take it as a premise
18 that the way that the mortality component of
19 SAMMEC works is that the mortality ratios from
20 the CPS II data that's published in the 1989
21 Surgeon General's report is put together with
22 estimates of smoking prevalence and applied to
23 deaths for the respective diseases. Would you
24 say that that is using CPS II data on a
25 subnational population?

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1 A. Yes, I would.

2 Q. So, to the extent to which that was a
3 decision -- strike that.

4 The extent to which the design of
5 SAMMEC reflects a decision on the part of the
6 Centers For Disease Control that CPS II results
7 are applicable on a subnational level, you would
8 disagree with it?

9 A. That's correct.

10 Q. To the extent to which the Surgeon
11 General of the United States has issued the
12 statement that smoking is a major cause of lung
13 cancer, you would disagree with it?

14 A. That's correct.

15 Q. To the extent to which the World Health
16 Organization through the International Agency for
17 Research on Cancer has issued statements that
18 smoking is a major cause of lung cancer, you
19 would disagree?

20 A. I would.

21 Q. To the extent to which the National
22 Cancer Institute has issued statements that lung
23 cancer -- strike that. That smoking is a major
24 cause of lung cancer, you would disagree with
25 that?

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1 A. I would. I would say in each case that
2 it may be a cause of lung cancer.

3 Q. And that statement, it may be a cause
4 of lung cancer, is different from the statements
5 that I have been describing?

6 A. Yes.

7 Q. Similarly, as to statements regarding
8 the causal relationship between smoking and lung
9 cancer issued by the American Cancer Society, you
10 would disagree?

11 A. Is that the same group you mentioned
12 before?

13 Q. I didn't think I had mentioned the
14 American Cancer Society.

15 A. I'm not sure what the precise statement
16 is they make.

17 Q. If that statement is smoking is a major
18 cause of lung cancer in the United States, you
19 would disagree?

20 A. I would disagree and say that it may
21 be.

22 Q. I won't go through the list again. But
23 would you have a similar answer if I simply
24 replaced the phrase lung cancer with coronary
25 heart disease?

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1 A. Yes, I would.

2 Q. Outside of the context of litigation,
3 have you expressed these opinions in writing?

4 A. I don't think so, no.

5 Q. And by these opinions you understand --

6 A. The opinions that we just discussed, my
7 opinion that it may be a cause of cancer or heart
8 disease.

9 Q. Rather than is a major cause of?

10 A. I don't recall writing anything in that
11 context.

12 Q. Have you ever expressed these opinions
13 to any of the epidemiologists who you mentioned
14 personally knowing at the beginning of the
15 deposition?

16 A. I don't think so, because I have known
17 them all in a relationship that goes back several
18 years. And the only one I've seen within the
19 past year has been David Savitz.

20 Q. And you didn't tell David Savitz that
21 you disagree with the Surgeon General of the
22 United States when he said smoking is a major
23 cause of lung cancer and heart disease?

24 A. It didn't come up. I was down there to
25 give a lecture on survey methods.

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1 Q. Would you agree that the issue of
2 whether smoking is a major cause of lung cancer
3 and heart disease in the United States is one
4 that concerns the epidemiological community?

5 A. That question took so long to get out,
6 I wish you would put it together for me.

7 Q. Is it an important issue to
8 epidemiologists?

9 A. Whether or not smoking is a cause --

10 Q. Whether or not smoking is a major cause
11 of lung cancer.

12 A. I think it's something the entire
13 medical community is concerned about, yes.

14 Q. But specifically those who are
15 concerned with epidemiological methods, is it an
16 important issue to them?

17 MR. DUNCAN: Objection as to form.

18 THE WITNESS: You'll have to tell me
19 what you mean by issue to them. In what context
20 would it be an issue to them?

21 BY MR. PICCIONI:

22 Q. That it matters to their thinking about
23 epidemiology whether or not the Surgeon General
24 or all of these other agencies are wrong when
25 they say that smoking has been shown to be a

1 major cause of lung cancer and heart disease?

2 MR. DUNCAN: Objection as to form.

3 THE WITNESS: I think I can speak not
4 for the epidemiologic community. I can speak for
5 myself as a practicing epidemiologist, that any
6 question such as that is a major issue. But the
7 importance of being precise about it is largely a
8 function of the use to which it's to be put.

9 If it is to be used to decide whether
10 or not you want to develop remedial programs and
11 do you want to have a smoking sensation --
12 cessation program be a part of a general health
13 policy, that's a rather inonerous kind of use to
14 which you're putting this, because individual
15 decisions will be made by practitioners in the
16 public health arts on down through the chain as
17 to whether or not that's going to be a part of
18 their day-to-day operations and how much of their
19 resources they're going to devote to it.

20 If, on the other hand, you are talking
21 about something in a more -- with a more
22 draconian result such as regulation, which I
23 spent 20 odd years at a regulatory agency, or
24 banning or restitution, anything where somebody
25 who is responsible in that process is going to be

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1 assessed in some way for their role, then I
2 personally feel it's absolutely essential that
3 you be on very firm ground and that you know
4 whereof you speak.

5 And this is why I tend to draw this
6 distinction rather consistently, about not
7 wanting to agree that smoking is the cause nor
8 even a cause of a disease when I know there are
9 other causes for that disease. I would say pin
10 that down for me and I will agree. But absent
11 that I cannot go beyond in my own mind thinking
12 that it may be and it warrants further
13 exploration.

14 BY MR. PICCIONI:

15 Q. Am I correct in understanding that your
16 response is consistent with the following, in the
17 context of civil litigation for reimbursement of
18 millions of dollars of healthcare expenditures,
19 the standard of proof required is high?

20 MR. DUNCAN: Objection as calling for a
21 legal conclusion.

22 THE WITNESS: I don't know what high
23 means. But I expect more proof than if something
24 is simply going to be used to develop a program
25 or a project, whether it's a national program or

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1 project or a local program or project.

2 BY MR. PICCIONI:

3 Q. Higher than a better than even chance?

4 MR. DUNCAN: Same objection.

5 THE WITNESS: I can't put that kind of
6 a criterion on it.

7 BY MR. PICCIONI:

8 Q. If those who are convinced that there
9 is a causal relationship between smoking and lung
10 cancer and coronary heart disease are wrong,
11 would that impact research into epidemiological
12 methods?

13 MR. DUNCAN: Objection as to form.

14 THE WITNESS: I'm trying to put the
15 question together again. It's a question with a
16 lot of time between the beginning and the end.

17 If those who believe that smoking
18 causes lung cancer and coronary heart disease are
19 wrong, would that impact resources dedicated to
20 epidemiology research?

21 BY MR. PICCIONI:

22 Q. No. Would it impact the thinking of
23 epidemiologists about epidemiological methods.

24 MR. DUNCAN: Objection as to form.

25 BY MR. PICCIONI:

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1 Q. Their validity, their utility?

2 A. I think it would, especially with
3 respect to the use of things such as attributable
4 risk in this context which carries with it the
5 requirement that all else be equal. And most of
6 them know for a fact that all they can do is
7 adjust for that statistically. They don't know
8 in point of fact that all else is equal.

9 Q. Would you disagree with the proposition
10 that the overwhelming majority of practicing
11 epidemiologists in the United States are
12 persuaded that the relationship between smoking
13 and lung cancer on the one hand, coronary heart
14 disease on the other, has been established as
15 more likely true than not true?

16 MR. DUNCAN: Objection as to form.

17 To the extent that the witness knows,
18 he can answer.

19 THE WITNESS: I don't know what the
20 overwhelming majority may believe in the context
21 of this litigation. I think the majority of
22 people I know in this field, as I alluded
23 earlier, are inclined to set a higher standard
24 for proof when there is a draconian action
25 contemplated than if it's merely for program

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1 guidance.

2 BY MR. PICCIONI:

3 Q. I attempted in my question to set what
4 that standard of proof was which was more
5 probably true than not true. Does that enable to
6 you answer the question?

7 MR. DUNCAN: Objection as calling for a
8 legal conclusion.

9 THE WITNESS: No, because -- I cannot
10 put a more probably than not on it. Most of us
11 in this field would like to be sure of the ground
12 we stand on before we do something.

13 I can speak only for the background I
14 have in regulatory agencies; that, as the
15 director of epidemiology, I wanted to be
16 absolutely certain that we had proof of cause and
17 effect before we banned or changed a product.

18 BY MR. PICCIONI:

19 Q. Can you name for me a single
20 epidemiologist practicing in the United States
21 today who you know is of the opinion that smoking
22 has not been shown on a more likely than not
23 basis to be a cause of lung cancer?

24 A. I know of one.

25 Q. Can you think of another one?

1 A. I know others with whom I've spoken
2 agree with the position I have taken in the
3 context in which I have taken it. And they are
4 practicing epidemiologists who cannot speak up
5 publicly because it is politically incorrect for
6 them to do so and their careers would be
7 destroyed.

8 Q. And you interpret what they said to
9 mean what I asked, that smoking has not been
10 shown on a more probable than not basis to be a
11 cause of lung cancer?

12 A. That's not quite the way the
13 conversation lined up. So the answer to that
14 question is no.

15 Q. The issue in these conversations that
16 you're making reference to had more to do with
17 the applicable standard of proof; is that
18 correct?

19 A. It had more to do with what I do for a
20 living. Tobacco litigation comprises a
21 reasonably substantial part of my income. And
22 they're curious as to what my stance is. I have
23 shared it with them. And they with no exceptions
24 have accepted my reasoning.

25 Q. Have?

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1 A. Accepted my reasoning.

2 Q. In your Ohio report, Doctor, Exhibit 1,
3 at page 11, the first full paragraph on that page
4 ends with a sentence. Could you read that
5 sentence. It starts with it is inconsistent.

6 A. Yeah, I'm just looking at the context.
7 It is inconsistent with the scientific method
8 and fallacious reasoning simply to assume that
9 either risk factor prevalence rates or relative
10 risks are the same in two discrete populations
11 without demonstrating empirically that they are
12 the same."

13 Q. That sentence is new to the Ohio report
14 in the sense that it's not in the Northwest
15 Laborers report?

16 MR. DUNCAN: Objection as to form.

17 THE WITNESS: It may be. I don't think
18 in the Northwest Laborers report I discuss CPS
19 II. I don't think anyway.

20 BY MR. PICCIONI:

21 Q. Forgive me for asking this question,
22 but that wording is entirely your own?

23 A. Yes.

24 Q. Is it inconsistent with the scientific
25 method and fallacious reasoning to assume that

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1 either risk factor prevalence rates or relative
2 risks are similar in two discrete populations
3 without demonstrating empirically that they are?

4 A. Why are you saying similar?

5 Q. I'm asking a question, whether you
6 agree with that statement.

7 A. It depends on the degree of similarity,
8 if similarity means for all practical purposes
9 the same.

10 Q. Then would it be inconsistent with the
11 scientific method and fallacious reasoning to
12 assume that they are similar in two discrete
13 populations without demonstrating empirically
14 that's the case?

15 A. Yes. I think you have to take a look at
16 what the source of the information is, what the
17 derivation of the risk factors are, and whether
18 or not they're comparable.

19 Q. Are any of the results from the NEISS
20 system used to reach conclusions that are applied
21 to populations that are not part of the NEISS
22 study?

23 A. Are any of the --

24 THE REPORTER: "Question: Are any of
25 the results from the NEISS system used to reach

1 conclusions that are applied to populations that
2 are not part of the NEISS study?"

3 THE WITNESS: No. NEISS doesn't really
4 lead to conclusions. NEISS is a case identifying
5 system essentially. It allows us to draw some
6 appreciation of what products are being treated
7 in hospital emergency rooms and it's used as a
8 form of administrative triage by that federal
9 agency and others who have bought into the system
10 to make a determination where they want to zero
11 in and take a closer look. But there are no
12 conclusions as to cause ever derived from NEISS.

13 BY MR. PICCIONI:

14 Q. But there are conclusions about where
15 to spend limited resources?

16 A. Where to look further, yes.

17 Q. And spend money that could be spent
18 elsewhere?

19 A. Well, you have to understand the way
20 the Consumer Products Safety Commission
21 operates. By looking further you go to the
22 second level of NEISS. There's a budget set
23 aside within the Consumer Products Safety
24 Commission for in-depth investigative follow-up.
25 And judgments will be made from NEISS

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1 based upon either the frequency of a particular
2 event coming in from the hospitals which are a
3 statistically valid set of hospital emergency
4 rooms across the nation to select a sample of
5 cases associated with a product that is very
6 frequently involved or a product that is involved
7 perhaps less frequently but with more serious
8 injuries.

9 Some of that investigative budget will
10 be applied to those to gather additional
11 information. Sometimes the information will be
12 quite simple, for example, to determine more
13 precisely the product that's involved. Since
14 there is an estimated ten to 15,000 products that
15 the commission is regulating, it's necessary to
16 have product codes which cover a wide variety of
17 them.

18 And originally, for example, we had a
19 code for recreational vehicle. It was only when
20 we saw the size of recreational vehicle injuries
21 being reported through the system increasing
22 rapidly that we created additional codes to get
23 greater precision and determine what kinds of
24 recreational vehicles. That's the nature of the
25 additional resources that are being spent.

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1 Once decisions are made as to whether
2 or not a product has a definable role in the
3 creation of an accident or an injury, a decision
4 will be made based upon those data which usually
5 are predicated on a combination of the
6 surveillance investigations and some engineering
7 studies and a recommendation will be made to the
8 commission who will make a decision.

9 And that decision will be predicated
10 partly on the data, partly on the politics of the
11 situation, and partly on the ability to do
12 something fairly rapidly about it.

13 Q. But in that process are the
14 participants limited to making decisions that
15 affect the populations under study by the NEISS
16 system; in other words, aren't they making
17 decisions that are based upon the inference that
18 observations made by the NEISS system or
19 follow-up observations based on other limited
20 populations apply generally to the U.S.
21 population?

22 A. No. They apply generally to the
23 product that's being looked at.

24 Q. A product in the hands of consumers
25 generally in the United States?

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1 A. Yes.

2 Q. So you don't, for example, say the
3 NEISS system is telling us that we're treating an
4 awful lot of kids for lawn dart injuries, but we
5 only know about the kids who are being treated in
6 the hospitals that are part of the system, we
7 know nothing about the kids that are being
8 treated in other hospitals?

9 MR. DUNCAN: Objection as to form.

10 THE WITNESS: That's not true. The
11 NEISS is a weighted probability sample. And as
12 such the cases that are reported through the
13 hospitals that participate in NEISS are
14 representative of cases being reported through
15 other hospitals.

16 BY MR. PICCIONI:

17 Q. Are they inferred to be exactly the
18 same as the cases that would be reported through
19 the other hospitals?

20 A. No.

21 Q. Would epidemiology be useful if the
22 results of an epidemiological study only applied
23 to the subjects of that study?

24 A. By subjects now are you talking about
25 the products or the victims?

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1 Q. The study subjects.

2 A. The study subjects are the products.

3 Q. Speaking more generally about
4 epidemiology as a science.

5 A. Well, I can't make the leap that you're
6 making then from the general science of
7 epidemiology to the subjects of people or
8 injuries reported through the NEISS. You'll have
9 to draw that distinction for me, I can't follow
10 your question.

11 Q. I'm speaking generally about
12 epidemiology as a science and asking you if the
13 utility of epidemiology as a science is not based
14 on the belief of epidemiologists that
15 epidemiological findings obtained from the study
16 of one population are applicable to other
17 populations?

18 A. To the extent that the study population
19 is statistically representative of the rest of
20 the population, of course it is.

21 Q. How do you decide whether the two
22 populations have that relationship, that the one
23 is statistically representative of the other
24 briefly?

25 A. Well, generally one has to be a

1 specifically selected subset of the other. If
2 you take two statistically valid samples in the
3 United States, they're not necessarily subsets of
4 one another, but they are both representative
5 sets of the master set which they're looking at.

6 In that case they probably can be
7 viewed in a joint context, but they are
8 statistically representative of some larger group
9 that they're looking at, both of them in that
10 case.

11 Q. So it's based upon the fact that the
12 one is a random sample from the other; am I
13 understanding this correctly?

14 A. Not necessarily a random sample -- that
15 the smaller population is a random sampling of
16 the other?

17 Q. Yes.

18 A. A statistically representative sample,
19 random is one way to get at that.

20 Q. And does the judgment that the one
21 population is statistically representative of the
22 other require specifying the degree of precision
23 required in the application of the results from
24 the one population to the other population?

25 MR. DUNCAN: Objection to form.

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1 THE REPORTER: "Question: And does the
2 judgment that the one population is statistically
3 representative of the other require specifying
4 the degree of precision required in the
5 application of the results from the one
6 population to the other population?"

7 THE WITNESS: I'm still not sure I
8 understand that question.

9 BY MR. PICCIONI:

10 Q. Sure. Let me give you an example.
11 Suppose the question is a qualitative one, is the
12 incidence of lung cancer higher in asbestos
13 workers versus other workers. And you have an
14 observation of lung cancer in asbestos exposure
15 in one population, but you want to answer that
16 question, that qualitative question, about
17 another population.

18 A. I'm right that that would require
19 considerations of statistical representativeness
20 that are different than the situation where you
21 wanted to develop an estimate of the statistical
22 association between asbestos exposure and disease
23 in that second population that was precise to 1
24 percent?

25 MR. DUNCAN: Objection as to form.

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1 THE WITNESS: I'm sorry, but this
2 question is just so convoluted I can't quite make
3 out what your precise question is. Is there some
4 way you can simplify it for me?

5 BY MR. PICCIONI:

6 Q. Sure, I will certainly try.

7 Don't we all extrapolate our
8 experiences made in one set of observations to
9 future events or events that take place under
10 other circumstances?

11 MR. DUNCAN: Objection as to the form.

12 THE WITNESS: I can't say what we all
13 do. From time to time, I do, yes.

14 BY MR. PICCIONI:

15 Q. But when a more precise answer is
16 required, we have to be more careful?

17 A. Yes.

18 Q. And part of what we have to be careful
19 about is whether our observations were made under
20 circumstances that are representative of the
21 circumstances that we want to apply that to?

22 A. Yes.

23 Q. So the degree of care that we have to
24 exercise or should exercise in your view in
25 taking observations from one context and applying

1 them to another depends upon the degree of
2 precision that we're asking for in the answer?

3 A. Yes, and the importance of the decision
4 that you make in the other condition. If it's
5 shall I go to the golf course or shall I go
6 sailing, it's not quite as important as should I
7 invest my money here or should I invest my money
8 there.

9 Q. So is it necessarily then inconsistent
10 with the scientific method and fallacious
11 reasoning to assume that risk factor prevalence
12 or relative risks are similar in two discrete
13 populations without demonstrating empirically
14 that that's the case regardless of the degree of
15 precision required of the comparison?

16 A. To my mind it's more or less important
17 depending on the application to be used. But, if
18 you're going to apply what you call a scientific
19 method or suggest that you're doing any kind of
20 analysis before making your decision, then it
21 should, in fact, be an analysis, it shouldn't be
22 just, oh, it looks the same here and it looks the
23 same there and let's go with it.

24 I wouldn't even do that in trying to
25 decide at a local county level whether or not I

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1 wanted to have a representative on the local
2 safety council or a representative on the city
3 council on that cavalier a basis.

4 I would try to decide what's more
5 important to me as an organization and how much
6 analysis would I have to do to decide where's the
7 best place to put my resource at that point. So
8 I think in science it's a good deal different
9 than everyday life.

10 Q. But if the question that's being posed
11 to the scientist is a question that inherently
12 does not require a precise answer, is it
13 inconsistent with the scientific method or
14 fallacious reasoning to use a methodology that
15 meets the precisional needs of that question?

16 MR. DUNCAN: Objection. Counsel has
17 asked that question about five times including
18 the times before. He still doesn't agree with
19 the way you're asking. I think it's been asked
20 and answered.

21 THE WITNESS: I can only say that, in
22 the scenario you're drawing here, if the decision
23 is a minor administrative decision, it probably
24 would not be inconsistent.

25 But the context of this sentence is

1 after discussion of Ohio Funds and the CPS II
2 population. So the context of the sentence here
3 is what I had in -- the context of the preceding
4 sentence is what I had in mind when I wrote
5 this. And I stand behind the statement.

6 BY MR. PICCIONI:

7 Q. And so the statement is to be read in
8 the context of your understanding of the degree
9 of precision required of this, the plaintiffs'
10 damages model?

11 MR. DUNCAN: Objection, misstates his
12 testimony.

13 THE WITNESS: I'm talking about here
14 differences in the population in the Ohio Fund
15 which are predominantly union members as opposed
16 to the CPS II population which are predominantly
17 middle to upper middle class white population
18 with a well above average education.

19 And these two populations are -- one
20 clear difference. And I'll warrant there are
21 several others that we could document. I say, if
22 you're going to analyze these data for any
23 scientific purpose, you should try to demonstrate
24 empirically that they are the same or precisely
25 how they differ so that you can try to adjust for

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1 them.

2 (Recess.)

3 MR. PICCIONI: Back on the record.

4 BY MR. PICCIONI:

5 Q. Doctor, when we were discussing before
6 what would be involved in doing a study of
7 expenditures in these funds, we were talking
8 solely about the issue of the accuracy of coding
9 of ICD-9 disease categories; is that correct?

10 A. Well, not really. I mean that's the
11 context in which the discussion came up. But
12 we're talking about the total array of data.
13 The accuracy of the ICD-9 categories is
14 certainly one part of it. The accuracy of
15 information on smoking through the National
16 Center for Health Statistics may also be a
17 question because that didn't necessarily break
18 down to what the smoking habits may be within
19 that population.

20 So I would say that it would be best to
21 know as much as you can about the two
22 populations. As far as the ICD coding goes, we
23 were talking about investigating individual
24 patients' medical records and so on. But it
25 would be best if all of the data were very

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1 specific to the population, the target
2 population.

3 Q. Your estimates of the amount of effort
4 involved pertain to the ICD-9 code checks?

5 A. Yes, largely.

6 (Verhalen-Ohio Exhibit No. 4
7 was marked for identification.)

8 BY MR. PICCIONI:

9 Q. Doctor, one of the papers that you cite
10 I believe in your report is a study, the first
11 author is Barendregt?

12 A. Yes, the New England Journal of
13 Medicine, a study entitled The Health Care Costs
14 of Smoking.

15 Q. Doctor, on page 1054 there is a figure
16 entitled Estimated Annual per Capita Health Care
17 Costs for Dutch Men in 1988 and for the Male
18 Population in a Life Table, According to Age and
19 Smoking Status; is that correct?

20 A. Yes.

21 Q. Is this figure pertinent to the issue
22 that this paper addresses, that is the reason why
23 you included it as one of your references?

24 A. The direct reference of information in
25 this article is less germane to any specific

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1 point in here than it might have been to an
2 earlier report. Many of these reports as I said
3 are covering the same ground.

4 And for the most part I am putting in
5 my bibliography articles that were reviewed and
6 are a part of my total background of knowledge on
7 these kinds of things when I come into these
8 studies. I cannot without reading it bring a
9 specific point out of here and point to it in the
10 study.

11 Q. So looking at this figure does not
12 bring to mind the reason why you cited this
13 paper?

14 A. No, it doesn't, it doesn't leap out.
15 The reason it was cited was because it was part
16 of the literature that we kept for this study and
17 two or three previous studies. I don't feel it's
18 appropriate to pull something out simply because
19 it's not very specifically germane to an issue
20 when it is a part of the total background.

21 Q. But there isn't any particular
22 statement or proposition in your report that the
23 Barendregt paper supports?

24 A. Not that come to mind immediately. I
25 would have to look at the article again.

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1 As I review the abstract, by way of
2 just trying to remind myself of what the details
3 of the article are, no, this was part of the
4 total background package, the point in this being
5 one that nobody really likes to talk about
6 openly, and that is that, if you did actually
7 stop all smoking, healthcare costs in total might
8 go up. But that's not an argument I'm trying to
9 make here.

10 Q. Why would they go up?

11 A. Because people live longer and they use
12 the medical care delivery system for many more
13 years than do smokers by and large. Smokers have
14 an earlier age of death.

15 Q. I don't understand. Why would the
16 costs -- under what circumstances would they go
17 up?

18 A. Because people live longer and at an
19 older age they tend to use the medical care
20 delivery system more than they did at a younger
21 age and the total healthcare costs would be as
22 high or higher than they would be than the
23 smoking costs normally.

24 It's not an argument that I'm trying to
25 make here, but it's an article that I thought was

1 interesting and I thought creates a very
2 interesting economic point. But I'm not an
3 economist, I'm not trying to promote this
4 particular position as a part of my --

5 Q. I'm just trying to understand what you
6 said and I'm a little confused.

7 A. Healthcare costs for smokers -- let me
8 read from the document.

9 Q. Yeah.

10 A. "Health care costs for smokers at a
11 given age are as much as 40 percent higher than
12 those for nonsmokers, but in a population in
13 which no one smoked the costs would be 7 percent
14 higher among men and 4 percent higher among women
15 than the costs in the current mixed population of
16 smokers and nonsmokers. If all smokers quit,
17 health care costs would be lower at first, but
18 after 15 years they would become higher than
19 present. In the long term, complete smoking
20 cessation would produce a net increase in health
21 care costs, but it could still be seen as
22 economically favorable under reasonable
23 assumptions of discount rate and evaluation
24 period."

25 The conclusion is that, if people

1 stopped smoking, there would be a savings in
2 healthcare costs but only in the short term.
3 Eventually smoking cessation may lead to an
4 increased healthcare cost. It's an interesting
5 economic argument.

6 Q. When you said cessation, do you mean
7 cessation?

8 A. Cessation, that's what I thought I
9 said.

10 Q. Now healthcare costs in the long run
11 then you are saying would go up if people stopped
12 smoking?

13 A. That's correct, total healthcare costs
14 for the population.

15 Q. And they would go up --

16 A. According to Barendregt, if people
17 stopped smoking, there could be a savings in
18 healthcare costs, but only in the short term.
19 Eventually smoking cessation would lead to
20 increased healthcare costs.

21 This is an argument nobody really likes
22 to promote because it sounds crass, and a reason
23 for objecting to some of the things that are
24 going on here may be to present the argument that
25 it actually costs more to keep people alive

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1 longer than to let them die younger.

2 To the extent that smoking may or may
3 not be responsible for that, it's a fact that the
4 longer one lives, the higher one's healthcare
5 costs go, just a basic economic fact of life
6 apparently.

7 Q. Can we look at that figure, figure 1 on
8 page 1054.

9 A. Yes.

10 Q. Is the concept that you were just
11 describing to me reflected in something like the
12 area under those two curves that go up and then
13 come back down?

14 A. Yes.

15 Q. And why does the dotted curve come down
16 before the one with the solid lines?

17 A. Well, you're talking about the age
18 group. If you look across the bottom, you've got
19 age bands ranging from 40 on up to 89. You've
20 got fewer people remaining in the population
21 requiring medical costs at age 75-79 among
22 smokers than you do among nonsmokers.

23 You're talking about an annual
24 population cost per capita of around \$4,500 with
25 a total population cost of around \$600 million

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1 for 75 to 79-year-olds, in a year for which the
2 nonsmokers among that group would be totaling
3 close to \$900 million or roughly \$7,000 per
4 person.

5 Q. The dotted line represents the smokers,
6 the solid line the nonsmokers?

7 A. That's correct.

8 Q. And the dotted line drops down earlier
9 than the solid line?

10 A. That's correct.

11 Q. And that reflects what phenomenon?

12 A. That reflects an earlier death among
13 smokers than among nonsmokers. Once someone
14 dies, they no longer have medical costs. Those
15 who survive continue having medical costs. And
16 they continue to increase to a high up around age
17 75-79 and then they begin to drop off.

18 Q. What would happen to the areas --
19 excuse me.

20 And the total population costs are
21 represented by the areas under these two curves;
22 is that correct?

23 A. That's generally the way one views
24 these. These are really midpoints of bar
25 graphs. Essentially, when you have a line chart

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1 like this, it's a form of histogram.

2 Q. Now, what would happen to the areas
3 under these two curves, the one for the smokers
4 and the one for the nonsmokers, if at the age of
5 65 all expenditures were reduced by 80 percent?

6 A. I don't know, I'm not an economist. I
7 mean I could hazard a guess, but that's outside
8 of my field.

9 Q. But just simply, if you numerically
10 look at this chart and just take every point that
11 lies to the right of age 65 and drop it down to
12 one-fifth of its value, how would the areas under
13 those curves compare?

14 MR. DUNCAN: Objection, asked and
15 answered.

16 THE WITNESS: I mean I can only say
17 what I said before, I'm not an economist.
18 Anything I would do would be conjecture, it's
19 outside of my field, because you really have to
20 understand this to get into discount rates and
21 everything else, if you want to do that. And I'm
22 not in a position to try to do any of that.

23 BY MR. PICCIONI:

24 Q. But the reason graphically, is this
25 correct, that the area under the solid curve, the

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1 one for nonsmokers, is greater than the area
2 under the dotted curve for smokers because the
3 area between the solid curve and the dotted curve
4 after 65 is greater than the area between the
5 dotted curve and the solid curve before 65; isn't
6 that true?

7 A. It may be. The shapes of the curves
8 would be again as I said the subject of some
9 conjecture. So I'm not sure exactly what would
10 happen. But if you were to decrease costs by 85
11 percent, I presume you mean by 85 percent for
12 smokers?

13 Q. No, for both. And it's 80 percent for
14 both.

15 A. And why would you want to do that?

16 Q. I'm just asking the question.

17 MR. DUNCAN: And it's been asked and
18 answered, objection.

19 THE WITNESS: I don't know. I'm really
20 not in a position to try to project these
21 numbers. I mean presumably everything would come
22 down, but I don't know how close the lines would
23 be or anything else. I would probably want to do
24 some arithmetic and draw a fresh chart. Perhaps
25 you can see it, I can't.

1 BY MR. PICCIONI:

2 Q. Well, the peak value for the nonsmokers
3 is roughly at what age?

4 A. Seventy-five to 79.

5 Q. And the value is?

6 A. \$7,000 per capita, \$900 million

7 population.

8 Q. So let's look at the population cost of
9 \$900 million. Just for the purposes of this
10 question, decrease that value to one-fifth of
11 that.

12 A. Which value?

13 Q. The close to \$900 million for the
14 population.

15 A. All right. Decrease it by 80 percent?

16 Q. Yes.

17 A. All right.

18 Q. And so on for each of the data points
19 for both the nonsmokers and the smokers for all
20 ages past 65.

21 MR. DUNCAN: Objection. Counsel,
22 you've asked this question, he said he doesn't
23 feel comfortable doing it, you've asked it
24 numerous times, asked and answered.

25 BY MR. PICCIONI:

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1 Q. You can answer.

2 A. I don't know, when I'm doing that, what
3 I'm doing to the numbers. I may be doing
4 violence to some economic theory. I'm not in a
5 position to try and do something like that and
6 make sense out of it.

7 Q. I'm only asking you a question about
8 this figure graphically. Graphically what would
9 happen to the area under those curves if you did
10 that?

11 A. They would both decrease.

12 Q. And would it still be true that, for
13 the whole period between age 40 and age 89, the
14 area under the solid curve would be greater than
15 the area under the dotted curve?

16 A. I have no idea. It might be. But it
17 might be closer, the two lines might be much
18 closer together. I don't know. Intuitively it
19 makes sense, but this is outside of my
20 knowledge.

21 Q. In this chart per capita costs are
22 always greater for smokers than nonsmokers, is
23 that true, at all ages?

24 A. Per capita costs, no, not in all ages,
25 because for smokers it's dropping considerably

1 after age 64.

2 Q. Per capita costs.

3 A. Yes. If you look at the left, it says
4 per capita costs. And that number is going down
5 on the dotted line.

6 Q. Let's make sure we're looking at the
7 same lines. I'm looking at the --

8 A. Okay. I'm sorry. I was looking at the
9 population cost curve. Per capita costs are
10 higher overall, yes.

11 Q. For all ages?

12 A. Yes.

13 Q. For the smokers.

14 We can go off the record.

15 (Discussion off the record.)

16 MR. PICCIONI: Let's go on the record.

17 We're marking Dr. Verhalen's report in
18 the Minnesota case as an exhibit, Exhibit 5.

19 (Verhalen-Ohio Exhibit No. 5
20 was marked for identification.)
21
22
23
24
25

1 MR. PICCIONI: I'm done.

2 (Whereupon, at 4:35 p.m., the taking of
3 the instant deposition ceased.)

4
5 _____
6 Signature of the Witness

7
8 SUBSCRIBED AND SWORN to before me this _____
9 day of _____, 19__.

10
11 _____
12 NOTARY PUBLIC

13 My Commission expires: _____
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